

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF IOWA  
WESTERN DIVISION

SECURITY NATIONAL BANK, as Conservator for JMK, a minor child, No. C11-4017-MWB

Plaintiff, Sioux City, Iowa  
vs. January 6, 2014  
8:03 a.m.

ABBOTT LABORATORIES, Volume 1 of 10

Defendant.

Sioux City, Iowa  
January 6, 2014  
8:03 a.m.

**REDACTED** TRANSCRIPT OF TRIAL  
BEFORE THE HONORABLE MARK W. BENNETT  
UNITED STATES DISTRICT JUDGE, and a jury.

## APPEARANCES:

## For the Plaintiff:

AMANDA BRANDY VAN WYHE, ESQ.  
TIMOTHY S. BOTTARO, ESQ.  
Vriezelaar, Tigges, Edgington,  
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613 Pierce Street  
Sioux City, IA 51102

STEPHEN C. RATHKE, ESQ.  
ROBERT J. KING, ESQ.  
Lommen, Abdo, Cole, King & Stageberg  
2000 IDS Center  
80 South Eighth Street  
Minneapolis, MN 55402

## For the Defendant:

JOHN C. GRAY, ESQ.  
Heidman Law Firm  
1128 Historic 4th Street  
Sioux City, IA 51102

DANIEL E. REIDY, ESQ.  
JUNE K. GHEZZI, ESQ.  
GABRIEL H. SCANNAPIECO, ESQ.  
KATHRYN L. DORE, ESQ.  
Jones Day  
Suite 3500  
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Chicago, IL 60601

## Also present:

Louise Deitloff  
Daniel Morrison

## Court Reporter:

Shelly Semmler, RMR, CRR  
320 Sixth Street  
Sioux City, IA 51101  
(712) 233-3846

1 (Proceedings convened outside the presence of the jury  
2 venire.)

3 THE COURT: Okay. Well, we're getting started late,  
4 but we need to get started, so I have a couple of things I need  
5 to take up, but I was just advised by Mr. King that he believes  
6 there's a problem in the verdict form, so it's a little bit late  
7 to be raising it, but let's -- let's hear what the problem is.

8 MR. KING: Your Honor --

9 THE COURT: You'll have to turn your microphones on.

10 MR. KING: I'm new at this. I'll come up. Your  
11 Honor, I was observing that the verdict form would call for the  
12 jury to pass on the plaintiff's theories of design and warning.  
13 Integral to those theories are issues that go to state of the  
14 art. And so the jury theoretically could find for the plaintiff  
15 on design and answer yes to the state of the art which would be  
16 irreconcilable in my view.

17 And I would suggest to the Court that a separate  
18 question on the verdict on state of the art is not necessary  
19 because the defense is available and can be argued in defense of  
20 the design and the warning claims.

21 For example, design and warning each call for  
22 reasonable safe alternatives, practical results that are  
23 available. But that's integral to the state of the art defense.  
24 So I'm just concerned that we have the potential for an  
25 irreconcilable verdict.

1                   THE COURT: What's the -- who's going to be responding  
2 for the defense?

3                   MR. REIDY: Dan Reidy will, Your Honor. Your Honor, I  
4 believe that we need a separate part of the jury verdict form  
5 that addresses the affirmative defense of state of the art, so I  
6 think we need to have that in here.

7                   THE COURT: And it seems to me in argument can't the  
8 plaintiff just point out that if they award -- can't you just  
9 point out what the jury should do to avoid an irreconcilable  
10 problem?

11                  MR. KING: Certainly we can argue it, but sometimes  
12 juries don't understand or don't follow. And so the point is  
13 that the verdict form gives the jury the ability to answer  
14 questions that are irreconcilable. That's all.

15                  THE COURT: Well, I think that's true, but if they  
16 answer it that way, it's not irreconcilable. You lose.

17                  MR. KING: So the jury could find a design defect  
18 claim, for example, and still find that the product was made to  
19 the state of the art. I don't understand how that can square  
20 given the definition --

21                  THE COURT: Well, because I thought we had all agreed  
22 that the affirmative defenses were going to be carved out in the  
23 verdict form and that I would determine the effect of the  
24 verdict form after the verdict. I thought that was the  
25 understanding and that's why it was set up this way. Now, maybe

1 I missed something.

2 MR. KING: I'm not speaking to the learned  
3 intermediary issue. That stays on the verdict form pursuant to  
4 your rulings. But I know that our initial submission on our  
5 verdict did not carve out the state of the art defense. And  
6 it's just my experience that you don't have a separate question  
7 on that because of this danger. That's all. But we can  
8 certainly argue it and hope for the best.

9 THE COURT: Well -- so yeah, I think you make a good  
10 point here. So why do we need it for state of the art?

11 MR. REIDY: Judge, I think that the statutory Iowa  
12 defense of state of the art, that we are entitled to have the  
13 jury consider that as an affirmative defense. And in order to  
14 have that reflected on the verdict form, we need it separately  
15 addressed on the verdict form. We can't have it built into  
16 whether or not they prove their elements of their claim and then  
17 not have the jury addressed -- it's instructed on.

18 THE COURT: Well, it's instructed on it.

19 MR. REIDY: Yeah, but --

20 THE COURT: But there's not a verdict form --  
21 well . . .

22 MR. REIDY: There's essentially, Judge -- on each of  
23 the claims, there's a part of the verdict form that addresses  
24 each of those, and on each of the affirmative defenses there's a  
25 part of the jury verdict form that addresses those. That was

1 the symmetry that I think we agreed upon with the Court to begin  
2 with, and I think it's one that we have to have. We have to  
3 have --

4 THE COURT: Well, you don't have to have it in the  
5 verdict form. You have to have it in the instruction.

6 MR. REIDY: Yes, although I think --

7 THE COURT: You cite me a case that says you have to  
8 have it in the verdict form. You don't even have to have a  
9 specific verdict form. I could use a general verdict. Do you  
10 find for the plaintiff? If so, how much? I could. I never do  
11 that. But you cite me a single case from any circuit that has  
12 ever said you have to have a separate verdict question for every  
13 affirmative defense.

14 MR. REIDY: I can't do that as I stand here.

15 THE COURT: Because you know it doesn't exist.

16 MR. REIDY: Well, I don't know actually whether it  
17 does or it doesn't.

18 THE COURT: Well, what do you think?

19 MR. REIDY: It may well be that it does not, Judge. I  
20 guess what I'm saying is that in order to have the affirmative  
21 defense appropriately considered and to reflect that  
22 consideration by the jury, we think it's very important that it  
23 be separately addressed on the verdict form.

24 THE COURT: Well, that's like saying -- the flip side  
25 of that is, to show you how ridiculous your position is, it's

1 like saying for every one of the plaintiff's theories I have to  
2 have a special verdict form on each of the elements to make sure  
3 that they've considered it so they answer to each element have  
4 you considered this, yes or no. Why is that any different?

5 MR. REIDY: I guess, Judge, I think that it's not the  
6 same to say that you have to have the verdict form address each  
7 element because the elements -- if the Court instructs you have  
8 to find all these elements and then on the verdict form they  
9 check I find on that claim, then it, of course, is assumed that  
10 they found on that element. I think to remove the affirmative  
11 defense of state of the art from the verdict form and then -- I  
12 mean, I don't think the instructions then even cover it as  
13 they're currently there.

14 THE COURT: What do you mean the instructions don't  
15 cover it?

16 MR. REIDY: Well, then the Court would have to tell  
17 the jury, you know, what the state of the art defense is which  
18 it does in its --

19 THE COURT: Well, I do that. I instruct on it.

20 MR. REIDY: Yes, of course. And then I think it would  
21 be very difficult to tell them then how to respond to the -- the  
22 jury verdict form, you know, where we have affirmative defenses  
23 broken out separately. And I think that if we're going to break  
24 the affirmative defenses out separately which I think is fully  
25 appropriate and which the Court had done in its original verdict

1 form that it makes sense to have each of them there. And we can  
2 address that. And if -- I mean, we have time to do this. We  
3 can also have the Court address it in an instruction as far as  
4 the risk or any risk of inconsistent verdicts.

5 THE COURT: Well, I would certainly have to change on  
6 page 31 the language in the instruction, not the definition of  
7 the state of the art defense but the effect of the state of the  
8 art defense. I'd certainly have to make that change.

9 Mr. Gray, do you have a view on this?

10 MR. GRAY: I do not, Your Honor.

11 THE COURT: Well, I think I'll leave it in. And, you  
12 know, it will just be up to the plaintiff to explain it  
13 effectively in the closing argument so that there isn't an  
14 inconsistency. You know, if it had been raised earlier, I might  
15 have done something else, but, you know, I instruct at the  
16 beginning, so we've gotta have these ready to go.

17 There are -- with regard to the instructions, we had  
18 inadvertently left out my instruction on questions by the jurors  
19 because I do allow the jurors to ask questions. I've just been  
20 doing that for the last year and a half or so. It's really been  
21 great. I'm not sure I've ever actually had an objection by the  
22 lawyers to a question. Usually average eight to ten questions a  
23 trial. They actually ask some really good questions. The  
24 lawyers often at sidebar will say to me, gee, I wish I had  
25 thought to ask that.

1                   And just so you know, here's how it works. At the end  
2 of every witness when the lawyers are done examining, I'll ask  
3 the jurors if they have any questions. If they do, they pass  
4 them down to the court security officer. They give it to me. I  
5 review them, and then I show them to the lawyers up at sidebar.  
6 We have a system where all the microphones are shut off. The  
7 noise keeps the jurors from hearing what we have to say. And I  
8 just have you state an objection. Like I said, I don't think  
9 I've ever had one, but if you have an objection, I would just  
10 rule on it just like I would any other objection.

11                  If I sustain the objection, obviously I'm not going to  
12 answer the -- ask the question. If there is an objection and I  
13 overrule it, I ask the questions of the witness. But after each  
14 question -- let's say there are more than one. Maybe there are  
15 three questions. I ask the question of the witness, and then I  
16 give the lawyers the opportunity to ask any follow-up questions  
17 directly related to that question. And I start with the party  
18 that has called the witness. Then I'll ask the next question,  
19 give the lawyers an opportunity to ask any follow-up questions.

20                  So any other objections or problems with the  
21 instructions that you want to make any record on at this time?

22                  MR. KING: Your Honor, for the plaintiff, may I speak  
23 from here?

24                  THE COURT: Absolutely.

25                  MR. KING: I think that we're on record on the -- our

1 view that there's not an evidentiary basis to support the  
2 learned intermediary defense. And my concern -- I'm aware of  
3 your view, and my concern always is unringing the bell. If you  
4 should decide at the time of submission that it shouldn't be in,  
5 they will have heard it. And I would just renew the objection  
6 and point out that we know of no evidentiary basis to support  
7 it.

8 THE COURT: Thank you. And if I ultimately conclude  
9 it, then I'll just ask the jury to cross it out. But I don't  
10 buy the ringing the bell theory, so I don't actually buy it in  
11 virtually anything including jury selection and everything else.  
12 So your objection's overruled, but I appreciate it.

13 Do you want to also -- are you satisfied that you've  
14 made a sufficient objection to the state of the art defense  
15 verdict form, or do you want to make any other record on that?

16 MR. KING: It's my view that if you believe there's a  
17 basis to submit state of the -- or I'm sorry, state of the art  
18 or --

19 THE COURT: I'm back to the original problem you had  
20 with the verdict form with regard to state of the art, and I  
21 just want to make sure you've had an adequate opportunity to  
22 make any record with regard to your objection on that.

23 MR. KING: Well, I trust that we've been on the record  
24 all along.

25 THE COURT: Yeah.

1                   MR. KING: And, therefore, I'm satisfied that the  
2 record is complete.

3                   THE COURT: All right. Thank you.

4                   MR. KING: Thank you, Your Honor.

5                   THE COURT: Which brings me to -- I think you would  
6 all be familiar with this rule, but because there are so many  
7 lawyers in this case, I don't allow tag team lawyering. You  
8 know, it's not the World Federation of Wrestling.

9                   So, for example, if Mr. Gray were to blurt out an  
10 objection during one of the plaintiff's witnesses, then he's  
11 going to be the one doing the cross-examination whether he  
12 intended to or not. And the whole point is that, you know, you  
13 can't have multiple people making objections. There's one -- I  
14 assume you've assigned one lawyer to each witness, so the lawyer  
15 that's going to be doing the cross-examination is the one that's  
16 going to be doing the objecting. And we're not trading off, in  
17 other words, so I think you all -- you all understand what I  
18 mean by no tag team lawyering? Yeah. And I'm sure you're all  
19 very used to that, so okay.

20                   You know, the major thing I haven't ruled on is this  
21 motion to seal. Is that going to come up today?

22                   MR. REIDY: We do not anticipate it coming up today,  
23 Judge.

24                   THE COURT: Okay. We are having a hard time  
25 finding -- when you filed the motion, you filed an Exhibit B

1 which allegedly said the documents that were subject to it were  
2 filed under seal. We can't find them anywhere, so do you have  
3 anything that actually lists the -- which exhibits are --

4 MR. REIDY: Let me just check, Judge.

5 THE COURT: Yeah.

6 MR. REIDY: Judge, we can certainly give you a list by  
7 tomorrow morning as well as a set if you would like of the  
8 Exhibit B documents. I don't think we have them broken up and  
9 at hand.

10 THE COURT: When do you think we're going to get to  
11 them? Will the plaintiff get to them in their case, or is it  
12 going to come up mostly in the defense case?

13 MS. GHEZZI: Well, Your Honor, we don't really know.  
14 I think it's probably going to come up --

15 THE COURT: In the plaintiff's case?

16 MS. GHEZZI: Yeah.

17 THE COURT: Yeah.

18 MS. GHEZZI: But I don't anticipate today, but it's  
19 hard to say.

20 THE COURT: Okay.

21 MS. GHEZZI: But probably not.

22 THE COURT: Okay. Here's another rule. You either  
23 need to wear a lapel mike or speak directly into the microphone  
24 because the acoustics are good with the microphones, but it's  
25 such a big barn that without the microphone the court reporter

1 and I -- even though you all can hear yourselves, we can't hear  
2 you.

3 MS. GHEZZI: Gotcha.

4 THE COURT: So it will be hard to get used to. And  
5 it's -- the light means that it's on. And in some courtrooms  
6 the default is on and you have to press the little bar. Ours is  
7 the opposite.

8 MS. GHEZZI: Okay. Thank you.

9 THE COURT: And if you're having a private  
10 conversation with the client, I notice the microphone's on, I'll  
11 ask you to shut your microphone off because it's hard to pay --  
12 you have so many things to pay attention to, it's hard to  
13 so . . .

14 You know, I might have been a little precipitous in  
15 my -- I mean, I do have this view that most of the claims of  
16 trade secrets really aren't. But I know you have some concerns  
17 because you know there's going to be a lawyer from a competitor  
18 that may be at the trial.

19 MS. GHEZZI: Well, I know that there is a lawyer from  
20 the competitor who has asked me on several occasions when it's  
21 going and stating that they'd like to be there as late as  
22 Friday. I did not answer that e-mail. But I don't know. I  
23 cannot represent to the Court that I know that somebody from the  
24 competitor will be here. But I can just say that that's what  
25 I've been told.

1                   THE COURT: Okay. Let me ask you this. Would it be  
2 sufficient do you think -- and please -- you know, you have to  
3 protect your client. That's not my job. I'm not looking out  
4 for your client's interest, I mean, only as a neutral but not as  
5 an advocate.

6                   But one of the things I thought of, we could certainly  
7 seal any record that you wanted in terms of the court filing and  
8 it would be under seal and nobody could go on Pacer and have  
9 access to it. Nobody could call the clerk and say, hey, we'll  
10 be glad to pay for a copy of that exhibit. And so I'm trying to  
11 draw maybe a balance here.

12                  But to the extent that witnesses testify about it, I  
13 don't mind actually sealing the transcript if you'll tell me  
14 when you think it needs to be sealed. We can seal that portion  
15 of the transcript so when the case is over and it's on appeal  
16 nobody could get access to the transcript. And that would  
17 obviate the need of trying to close the courtroom physically and  
18 exclude people. But maybe that isn't enough of a protection for  
19 you and your client. And you're in a better position to make  
20 that judgment really than I am.

21                  MS. GHEZZI: You know, Your Honor, I think that as it  
22 develops organically we can sort of see. I don't know what  
23 they're going to use. And our client is here, and if we see --  
24 if I see a lawyer from the competitor that I know, I can point  
25 that out. You know, we can do that kind of thing.

1                   THE COURT: And generally as you can see, we don't  
2 have a huge audience watching our trials.

3                   MS. GHEZZI: Yes. I'm blaming that on the weather.

4                   THE COURT: Well, blame it on lack of interest or how  
5 boring our trials are. I'm kidding. So if you're comfortable  
6 kind of playing it by ear, we can do that. You know, I don't  
7 want to harm your client with the release of any trade secret.

8                   MS. GHEZZI: I understand.

9                   THE COURT: But I'm kind of wondering, even if the  
10 lawyer's sitting in the office and somebody's talking, how much  
11 of it could he actually take down that would -- I don't know.  
12 But I'm open to sealing the courtroom if we have to.

13                  MS. GHEZZI: Okay.

14                  THE COURT: Okay?

15                  MS. GHEZZI: Thank you, Judge.

16                  THE COURT: Because even though I'm skeptical of trade  
17 secret claims, you know, this is a product where I could  
18 understand that there would be some legitimate trade secret  
19 claims. And I was looking at some documents, but I don't think  
20 I looked at the right documents. And then when I went this  
21 weekend to look at the documents you identified in Exhibit B, we  
22 couldn't find Exhibit B. It was probably just -- I don't know  
23 what the problem was. I'm not blaming it on anybody. But -- so  
24 I don't really feel I've reviewed the doc -- I know I haven't  
25 reviewed some of the documents, so I'm not really in a position

1 to say, hey, they're not trade secrets because I haven't  
2 actually reviewed them. I'm not sure I'd know it even if I did.  
3 But -- so I'm more willing to close the courtroom if it'd be  
4 relatively limited number of times and on limited evidence. But  
5 you'll -- so we'll just play it by ear, and you'll give me a  
6 heads-up; okay?

7                   What do you all have on your agenda?

8                   MR. BOTTARO: Your Honor --

9                   THE COURT: It's good practice. Just look for the  
10 light.

11                  MR. BOTTARO: I see. I thought the light was on.  
12 There was a story in the paper this morning. I don't know if  
13 you saw it.

14                  THE COURT: Yeah, I saw that.

15                  MR. BOTTARO: Would you address that with the jurors  
16 because I --

17                  THE COURT: Yeah, I will. Yep. Let me ask you this.  
18 Did both sides have an opportunity to see the story?

19                  MR. REIDY: (Nodded head.)

20                  THE COURT: I saw it, but I just kind of skimmed it  
21 real quickly. Is there anything in the st -- let me ask you  
22 this. Is anybody going to be overly concerned about the fact --  
23 actually I think you'll be surprised at how few people read the  
24 newspaper. But if they read the story, is any -- is either  
25 party taking a position that the mere reading of the story would

1 be enough to exclude someone from the jury?

2 MR. BOTTARO: Not on the plaintiff's side, Your Honor.

3 MR. REIDY: Nor on the defendant's side, Judge. I  
4 think that if the Court just satisfies itself and us that the --  
5 or I guess itself in this case that the juror --

6 THE COURT: Well, no, you too because you're  
7 ultimately --

8 MR. REIDY: Yes. You'll obviously decide that. But I  
9 think we'd be looking, Judge, just to make sure that, you know,  
10 it didn't create any predisposition that's a problem.

11 THE COURT: Right.

12 MR. REIDY: That's all.

13 THE COURT: And that's what I'll look for. Great.  
14 But no, I'll be glad to -- I'll be glad to raise that.

15 MR. BOTTARO: And, Judge, when you ask or when we  
16 introduce ourselves and whom we practice with and witnesses that  
17 may be called, do you then ask any follow-up on that?

18 THE COURT: Yeah, I'll ask who they know. And the way  
19 I've got it set up is -- normally -- I was trying to cut down my  
20 involvement so that the lawyers would have more time because I  
21 really believe in lawyer-conducted voir dire. So I was just  
22 going to kind of introduce the lawyers and then find out if  
23 anybody knows anybody. And then we'll go beyond if they know  
24 them how that might, if at all, affect. And I didn't really  
25 have the witnesses in there. I thought I'd let the lawyers do

1 that when I turn it over to you all. You can go through who  
2 your witnesses are and see if any of the jurors know them. I  
3 mean, most -- it seems like a ton of the witnesses are  
4 out-of-state experts. But stranger things have happened  
5 actually.

6 MR. BOTTARO: Right.

7 THE COURT: So I actually wasn't going to address the  
8 witnesses. I was going to leave that for the lawyers to do.

9 MR. BOTTARO: And as far as objections or challenges  
10 for cause, do you prefer us to stand or remain seated or -- when  
11 we address the Court?

12 THE COURT: I don't care.

13 MR. BOTTARO: Okay.

14 THE COURT: I think you can remain seated is fine.  
15 But if you want to stand, that's fine. Doesn't make any  
16 difference to me.

17 MS. GHEZZI: Judge, I have one question.

18 THE COURT: Yes.

19 MS. GHEZZI: Do you let them know maybe after they're  
20 empanelled that sometimes people at the tables will leave the  
21 room and come back?

22 THE COURT: Yeah. Thank you. I think what I'll  
23 explain is that while you all can come and go the jurors and I  
24 can't. But that's the rule. People in those tables, they get  
25 to come and go. Sitting here and sitting there, we stay. But

1 no, that's very -- yeah. Of course, I'll explain that, and  
2 thank you for raising that.

3 Anything -- are there other things we need to talk  
4 about or . . .

5 And on the PowerPoint slides, I'm not going to read  
6 every -- I'm not going to read every city that Jones Day has  
7 offices in, but I don't think it's enough to just say do you  
8 know the lawyer -- do you think you know anybody that works for  
9 Jones Day because that might not -- so I've got the cities in  
10 there. I'm not going to spend a whole lot of time on it. I'm  
11 just going to say it's a large firm with a lot of offices. Here  
12 are the cities they operate in, just leave it up there for --  
13 you know, I'm not going to dwell on it and go through every  
14 single city but . . .

15 MR. REIDY: We understand, Judge. And if it might be  
16 consistent, I think Mr. Rathke's firm has offices in Huron,  
17 Wisconsin, and New York City.

18 THE COURT: Oh, I didn't realize that.

19 MR. REIDY: So -- I believe I'm right on that. I  
20 looked on their website.

21 MR. KING: Your Honor, we do have an office --

22 MR. REIDY: Their website lists those two offices.

23 MR. KING: We do have an office in New York City.  
24 It's about as big as this table, but you're welcome to mention  
25 that to the court.

1                   THE COURT: Okay. Do you have an office anywhere  
2 else?

3                   MR. KING: In Hudson, Wisconsin.

4                   THE COURT: Okay. I'll just go ahead and add that  
5 physically to my PowerPoint. Thank you for pointing that out.

6                   MR. BOTTARO: We don't have any offices in Dakota  
7 Dunes or anything like that so . . .

8                   THE COURT: Or North Sioux.

9                   MR. BOTTARO: Or North Sioux, yeah.

10                  THE COURT: Yeah, no tri-state.

11                  MR. GRAY: Your Honor?

12                  THE COURT: Yes.

13                  MR. GRAY: I suppose -- and I'd forgotten it, but we  
14 now have just opened an office in South Sioux City.

15                  THE COURT: That -- okay.

16                  I want to make sure I can pronounce the lawyers' names  
17 correctly. And let me actually pull up that slide. So is it  
18 Reidy or "ready" or something else? I'm sorry. You've said it  
19 a number of times for me.

20                  MR. REIDY: First guess was the correct one, Judge,  
21 Reidy.

22                  THE COURT: Reidy, thank you.

23                  And Ghezzi?

24                  MS. GHEZZI: Yes, Your Honor. Yes, Ghezzi. I always  
25 like to say it's --

1                   THE COURT: And, Gabriel, you're going -- Gabriel,  
2 you're going to really have to help me out on yours so . . .

3                   MR. SCANNAPIECO: My last name's pronounced  
4 Scannapieco.

5                   THE COURT: Scannapieco?

6                   MR. SCANNAPIECO: Yes, Scannapieco.

7                   THE COURT: Scannapieco.

8                   MR. SCANNAPIECO: Yes.

9                   THE COURT: Is that close enough, or is that -- I  
10 don't want to get close. I want to try and get it.

11                  MR. SCANNAPIECO: That's dead on.

12                  THE COURT: Okay. Thank you.

13                  And is Mr. Morrison sitting next to you? Yes. He's  
14 the Abbott rep?

15                  MR. MORRISON: Good morning, Your Honor. Yes.

16                  THE COURT: Good morning. Welcome.

17                  MR. MORRISON: Thank you.

18                  THE COURT: Thank you. The two-week trial estimate,  
19 it's so hard to estimate, particularly the longer the trial  
20 the -- you know, it's pretty easy to estimate a two-day trial.  
21 The longer you get out, very hard to estimate. And I'm not  
22 super concerned even though I have a patent case that's  
23 allegedly starting the day this ends, the next day that starts,  
24 and I think we've scheduled it for -- is the 21st a federal  
25 holiday? Yeah. So I think that's probably supposed to start on

1       Tuesday, the 22nd, although maybe we're starting on a federal  
2       holiday because I often do. But you think we'll be done in two  
3       weeks or not? I -- you know, it's an important case. I was  
4       originally going to put you on a time clock. I don't think  
5       I'm -- I'm not going to do that. But I mostly want to know what  
6       to tell the jurors. I'm less concerned about the patent case  
7       because they only have like six witnesses. So -- yes, Mr. Gray?

8                    MR. GRAY: Your Honor, I think the holiday, wouldn't  
9       that be Monday, the 20th?

10                  THE COURT: Okay. The 20th?

11                  MR. GRAY: Yeah.

12                  THE COURT: Yeah, yeah. Thank you. So we're going to  
13       start on the 21st I think. But this case could certainly  
14       deliberate or we could have closing arguments on the holiday.  
15       We're not going to take the holiday off if this case is still  
16       going, but I assume you don't want this case to still be going  
17       by then but . . .

18                  MR. BOTTARO: We don't want it, but I think it's  
19       probably wise just to say there's a potential that it could go  
20       beyond two weeks.

21                  THE COURT: That it could go into the third week,  
22       particularly with deliberations.

23                  MR. REIDY: I think that would be the safe course,  
24       Judge, as well.

25                  THE COURT: Okay. Thank you.

1 MS. GHEZZI: And Judge?

2 THE COURT: Yes.

3 MS. GHEZZI: This might be a good time to raise this.  
4 We have one expert witness who is 71. His wife is about the  
5 same age. She, he informed me recently, is handicapped, and she  
6 can't travel alone. And he has to -- when we -- since August we  
7 told all of our people we're going to be on the clock and this  
8 is when we're going to go. And so we had said we're going to  
9 put him on early in the case, and we thought we'd put him on  
10 right at the beginning of the first -- of the second week. And  
11 so he sort of arranged that with his wife.

12 And he has to travel like from Sioux City back to  
13 Florida, pick her up and take her to Chicago because she cannot  
14 travel alone. And so this is the only person we might have an  
15 issue with in terms of seeking leave to take him out of turn if  
16 he can go on Monday, the 13th.

17 THE COURT: Absolutely. Absolutely.

18 MS. GHEZZI: Okay. Okay. Thanks, Judge.

19 THE COURT: We'll take him whenever -- just give me a  
20 heads-up like the day before.

21 MS. GHEZZI: Okay.

22 THE COURT: And we'll take him --

23 MS. GHEZZI: Thank you. We appreciate that, and he  
24 will appreciate it.

25 THE COURT: Yeah, we do that all the time. Sure. Any

1 chance you want to call him by video so he doesn't have to  
2 travel?

3 MS. GHEZZI: No, I don't think so.

4 THE COURT: Okay.

5 MS. GHEZZI: I think where he is, you know -- yeah.

6 THE COURT: Yep. You've got him scheduled, but  
7 absolutely, we'll take him out of order.

8 MS. GHEZZI: Thank you.

9 THE COURT: And if it comes up for other witnesses  
10 too, I know they're expensive to have sitting around, and so if  
11 we need to take people out of order, we'll do it to accommodate  
12 their schedules, so that's fine.

13 MS. GHEZZI: We do have one witness who probably will  
14 be remote. But Gabe has worked it out so -- with your staff.

15 THE COURT: Okay. That's fine. Anything on the  
16 plaintiff's agenda that we need to talk about?

17 MR. RATHKE: As the Court knows, we're going to read  
18 some depositions. And my plan is to have people to my left play  
19 all of the parts. I certainly was not going to ask Ms. Ghezzi  
20 to read her part, but if she would like to, that would be fine  
21 too.

22 MR. BOTTARO: We could certainly then read our parts  
23 if they're doing the same thing with witnesses.

24 THE COURT: Do you have any desire to read your part?

25 MS. GHEZZI: No.

1 MR. REIDY: Zero.

2 MR. RATHKE: Okay. We'll have someone --

3 THE COURT: I like the definitive nature of the  
4 statement. There's no ambiguity there.

5 MR. RATHKE: We'll have someone play Miss Ghezzi.

6 THE COURT: Okay. Anything else from the plaintiff?

7 Is there -- is there -- like are there lead  
8 counsels --

9 MR. SCANNAPIECO: Your Honor?

10 THE COURT: -- that I -- if I don't know who to call  
11 on I should be calling on?

12 MR. SCANNAPIECO: Excuse me, Your Honor. For purposes  
13 of counter designations, should we be reading those in? Are  
14 you -- at the same time?

15 MR. RATHKE: We'd be happy to read them in.

16 MR. BOTTARO: Well, but if they read theirs . . .

17 MR. REIDY: I think we'll just read -- if it's okay  
18 with the plaintiffs, we'd just read the -- whoever's reading it  
19 will read both the designations.

20 THE COURT: Will read both the designations and the  
21 counter designations. Do you have any problem with that?

22 MR. RATHKE: No.

23 THE COURT: Okay. I think that makes the most sense.

24 MR. BOTTARO: As to your question, Your Honor,  
25 Mr. Rathke is the lead counsel on the plaintiff's.

1 THE COURT: Okay.

2 MR. REIDY: Judge, I'm the oldest lawyer on our side,  
3 so we'll use the oldest test.

4 THE COURT: Okay. Thank you. Any -- now let's go to  
5 the defense. Anything on your agenda?

6 MR. REIDY: No, Judge, we don't have anything.

7 THE COURT: Okay. Thank you.

8 You know, it's awkward, but I need to bring it up.

9 This whole potential sanctions issue, you can look through my  
10 record. I think you can count on less than one hand the number  
11 of times I've sanctioned lawyers in 20 years. I was pretty  
12 shocked when I read through the depositions, and just to make  
13 sure my views weren't as idiosyncratic as they often are, I ran  
14 it by another judge which I never do, Judge Strand, and he was  
15 even more incensed than I was. And lawyers do that because  
16 judges look the other way. And I'm not the type of judge that's  
17 willing to look the other way. But I haven't given you in my  
18 view sufficient notice. I mean, I just thought there were so  
19 many obstructionist, frivolous objections that it was beyond  
20 anything I have ever seen.

21 And, Mr. Rathke, both Judge Strand and I commented  
22 that we don't know how you kept your patience with all that  
23 nonsense that was going on because neither he nor I would have  
24 put up with it either as a lawyer or as a judge.

25 So I think what I'll do is one -- at the end of the

1 day one of these days I'm going to give you some more specific  
2 notice. I'll probably just pick out one deposition because the  
3 conduct was, I thought, repeated often, but I -- on the other  
4 hand -- well, and then we can hold a hearing maybe next week in  
5 the evening and give you a chance to respond to it. It's just  
6 not something I think I can overlook so . . .

7           But I do want to give you more notice, so we'll just  
8 probably have a half-an-hour session one evening, and I'll go  
9 through what I thought the problems were.

10           Okay. We'll see you at nine.

11           MR. BOTTARO: Judge, since we're starting at nine this  
12 morning, when do you anticipate the mid-morning break?

13           THE COURT: The mid-morning break will be at 10:30.  
14 That's usually when I take the break. It's a little earlier  
15 than normal because people often have had coffee, and so their  
16 bladders are -- try and be practical. Their bladders require an  
17 earlier break.

18           Now, when we get -- you know, today we'll probably go  
19 till 4:30 or so, quarter to 5, something like that. Then  
20 tomorrow we go to the 8:30-to-2:30 schedule, and we'll be taking  
21 the mid-morning breaks anywhere between 10 and 10:15 usually and  
22 the afternoon break between noon and 12:15. And we'll probably  
23 take a 25-minute break. And, you know, you can feel free to  
24 have food brought in and eat right at counsel table if you want  
25 to. And the jurors will have goodies downstairs in the jury

1 room.

2 MR. RATHKE: Since we're going to later in the  
3 afternoon, will there be a lunch break?

4 THE COURT: Today?

5 MR. RATHKE: (Nodded head.)

6 THE COURT: Intravenous feeding tubes. You know, it's  
7 kind of like on the airline when they ask you to check for the  
8 flotation cushion. Just reach under your -- yep. You see it  
9 there, the feeding tube?

10 MR. RATHKE: I got it.

11 THE COURT: Okay. No. We'll be taking an  
12 hour-and-15-minute lunch break today.

13 MR. BOTTARO: I'm glad you clarified that. I thought  
14 that was the catheter, so it's the feeding tube.

15 THE COURT: Oh, right.

16 MR. BOTTARO: Thank you, Judge.

17 THE COURT: Or the enema. Okay. We'll see you back  
18 here at nine. Thank you.

19 MR. RATHKE: Thank you, Your Honor.

20 (Recess at 8:40 a.m.)

21 (The jury venire entered the courtroom.)

22 THE COURT: Good morning, everybody. How excited are  
23 you to be here this morning? Awesome. If you'd raise your  
24 right hand, I'm going to swear you all in.

25 (The jury venire was sworn.)

1 (Voir dire was reported but not transcribed.)

2 (The jury was sworn.)

3 THE COURT: Okay. Thank you. Please be seated.

4 Mr. Sun and Miss Ford, why don't we have you move to the back  
5 because we just have two lonely jurors back there. And that way  
6 that will give us four in the front row and four in the back  
7 row. And then why don't you slide down so you can be in the  
8 middle. Yeah, that's fine. It doesn't have to be -- I guess  
9 there's no exact middle but -- Lisa, you want them to move down  
10 one? Miss Kilberg, if you could move down one, that'd be great.

11 And notice there are cup holders. I'm proud of the  
12 fact that we're the first federal courtroom in the United States  
13 to have cup holders that I'm aware of, and I'm pretty sure I'm  
14 right about that. And that came about as a result of a juror  
15 quite a few years ago raising her hand in the middle of trial  
16 and saying why do the lawyers have things to drink, why does the  
17 witness have things to drink, why do I have things to drink and  
18 we don't have any? So we changed that. So you can bring  
19 anything you want into the courtroom as long as it's  
20 nonalcoholic. We save the alcohol for the lawyers. But the  
21 jurors, you know -- no, I'm just kidding. As long as it's  
22 nonalcoholic.

23 So here's what we're going to do. We're going to be  
24 in recess until 1:15. When you come back at 1:15, you will have  
25 a set of jury instructions, and then it's my obligation under

1 the law to go through these with you which I will. And then  
2 you'll also have a notebook and a pen because you're allowed to  
3 take notes if you want to. I actually have an instruction on  
4 note taking. You don't have to take notes. Nobody's going to  
5 read your notes. But if you want to take notes, you can. And  
6 sometimes I think it's easier to just take the notes right on  
7 the jury instructions if you want to. But it's really totally  
8 up to you whether or not you take notes or you don't take notes.

9                   And I wanted to talk to you about the schedule. Today  
10 we're going to go till about somewhere between 4:30 and quarter  
11 to 5 if we can have maybe a natural break or are done with a  
12 witness. But our schedule the rest of the week and next week, I  
13 hope you'll find it to your liking.

14                   When I first started as a federal district court judge  
15 20 years ago, I had 2 pretty lengthy trials. Matter of fact, my  
16 first trial was a patent trial. And I did a questionnaire for  
17 the jurors to find out which -- so we went a couple of weeks  
18 doing the traditional kind of 9-to-5 which we're doing today and  
19 then what I call my alternative schedule where we go 8:30 to  
20 2:30.

21                   And so that's -- we're going to use the 8:30 to 2:30  
22 the rest of this week for 2 primary reasons. Well, actually  
23 there's more than that. There's really maybe three or four good  
24 reasons.

25                   Particularly in the winter when it gets dark early, I

1 like the jurors to be able to get home early. I find that more  
2 people can serve on juries when they can get home particularly  
3 if you have kids, so it works better. Jurors unanimously like  
4 the 2:30-to-4:30 sch -- I'm sorry, the 8:30-to-2:30 schedule  
5 better every time I survey jurors, so I know you like it better.  
6 I actually don't like it, but it's really efficient, and I have  
7 a bunch of things scheduled in the afternoons, criminal cases,  
8 sent -- mostly sentencing. And while I'm sure the defendants  
9 aren't that anxious to be sentenced, I'm anxious to get those  
10 resolved and have those go on their way. And so that's another  
11 reason but not the primary reason.

12 I also think it's better for the lawyers. Lawyers  
13 work really hard getting ready for trial and really hard when  
14 they're in trial. And so this way they don't have to stay up  
15 quite as late at night. They can -- we have a lot of  
16 out-of-Sioux City lawyers. They can call back to their offices,  
17 deal with other client emergencies, and it just I think works  
18 better for the lawyers because they're fresher.

19 And it's kind of like skiing for those of you who have  
20 been downhill skiers. You know, about 70 percent of the  
21 accidents in skiing happen after 3:00. And I've often said  
22 during jury trials not much good happens after three. The  
23 lawyers are tired. They get irritable. I'm always irritable,  
24 but I get a little more irritable. And the jurors, it's just  
25 hard to pay attention for that long. So I think you'll find the

1 8:30-to-2:30 schedule will work to your benefit certainly on the  
2 back end. You know, you do have to get here a little bit  
3 earlier on the front end.

4                   And in terms of efficiency -- we've actually tracked  
5 it with the transcript pages -- it's just as efficient going the  
6 8:30-to-2:30 schedule as doing the longer schedule. You just  
7 compact the time, but you're just more efficient.

8                   So you obviously need breaks. We'll generally take a  
9 break anywhere between 10 and 10:15, and that will be a  
10 25-minute break, and then we'll take another one between noon  
11 and 12:15 in the afternoon, so there will just be two breaks.  
12 We should have snacks down there for you, but if you don't like  
13 what we bring, there's a refrigerator and microwave, and you can  
14 bring stuff if you need to eat.

15                   Let's see. I'm just drawing a blank here.

16                   Okay. Obviously one of the things I'm going to tell  
17 you repeatedly during the trial is keep an open mind till you've  
18 heard all of the evidence. It's very important that you do so,  
19 and you can't discuss this case among yourselves. Don't let  
20 anybody talk to you about the case. If they do, report it to  
21 me. And once all the evidence is over and you hear the closing  
22 arguments of the lawyers to summarize and interpret the evidence  
23 for you, receive my final instruction and go down to the jury  
24 room to deliberate, then you can talk about it as much as you  
25 want to with each other.

1                   So we will see you back here at 1:15. It's about five  
2 minutes to noon now, and we'll start back at 1:15.

3                   Here's what's going to happen this afternoon. I'll go  
4 over the jury instructions with you, and then we'll hear the  
5 opening statements of the lawyers. Opening statements are not  
6 evidence, but they're an opportunity for the lawyers to  
7 summarize what they think the evidence in the case will be. And  
8 then hopefully we may get through a witness or two or at least  
9 start with a witness.

10                  And then we'll just go through all the plaintiff's  
11 witnesses, then go through all of the defense witnesses, see if  
12 the plaintiff has any what we call rebuttal witnesses and then  
13 hear the closing arguments of the lawyers and you'll be able to  
14 deliberate. But that's probably not going to be till the end of  
15 next week at the very earliest.

16                  So congratulations. That's one of the things I'm  
17 going to tell you in the instructions. You've been selected to  
18 serve the United States of America as federal jurors. It's a  
19 very, very important duty.

20                  Oh, yeah. There was one thing I did want to tell you.  
21 At the end of the case when you're done with your deliberations  
22 and hopefully you've been able to reach a unanimous verdict, you  
23 know, one way or the other, I'm going to come down, and I'm  
24 going to meet with you, and I'm going to try and answer any  
25 questions that you might have. I've been doing this for 20

1 years. And I'm going to give you a questionnaire. And you're  
2 going to get to -- you don't have to fill it out. We don't keep  
3 you captive, but it's in an envelope, and you'll take it home.  
4 And hopefully most of you or all of you will fill it out. And  
5 you get to evaluate me as a trial judge, whether I've done a  
6 good job, whether I've been fair to both sides. You get to  
7 evaluate all of the lawyers in the case on a number of criteria.  
8 And I take that very seriously.

9 We've made huge changes in how our court does business  
10 based on the feedback we get from you. So it's very important  
11 for us to get that feedback, and it's very important for the  
12 lawyers because lawyers who try cases in federal court are very  
13 dedicated to their craft, and they're always trying to improve  
14 and get better. So honest feedback from you will be very  
15 helpful to them. So hopefully you have that to look forward to  
16 at the end of the trial.

17 So we do start -- I think you'll find we start pretty  
18 promptly. And so if you could be back just a couple of minutes  
19 early so we could start at 1:15, that would be great. Thank  
20 you. We'll see you back at 1:15.

21 (The jury exited the courtroom.)

22 THE COURT: Thank you. Please be seated.

23 Anything we need to take up from the plaintiff?

24 MR. RATHKE: Do you want the jury questionnaires  
25 returned? I'd be happy to do it. I don't want them.

1                   THE COURT: Yeah, if you don't want them. We have  
2 a -- recycling, so that'd be great. You can just give them to  
3 Matt. If you keep them, you get to come back and try the patent  
4 case.

5                   Mr. Gray, I think I'm going to appoint you to be in  
6 that case, you know. That will be your third one in a row.

7                   MR. RATHKE: So how long do you think your  
8 instructions will last?

9                   THE COURT: Will last?

10                  MR. RATHKE: Yeah.

11                  THE COURT: In perpetuity.

12                  MR. BOTTARO: Will take.

13                  THE COURT: Right. About 45 minutes probably. That's  
14 just a guess, but, you know, they're pretty lengthy. Or, you  
15 know, instead of me doing it, we could have the lawyers mime  
16 them. I'm real big on miming. So any volunteers from the  
17 lawyers to mime?

18                  Mr. King, you want to develop your forensic skills by  
19 miming the jury instructions?

20                  MR. KING: I'm rusty. I'm too rusty.

21                  THE COURT: Okay. Mr. Bottaro?

22                  MR. BOTTARO: I volunteer Ms. Ghezzi.

23                  THE COURT: There you go. Oh, yeah, but you can't  
24 volunteer the other side. That's the only thing so -- okay.  
25 Anything else we need to take up? We'll see you back here at

1 1:15. Okay. Thank you.

2 (Lunch recess at 12:01 p.m.)

3 THE COURT: Do you know if the jurors are all ready?

4 CSO STECKELBERG: They're ready.

5 THE COURT: Okay. Just a second here. Okay. Ready  
6 to have the jurors brought in?

7 MR. BOTTARO: Yes, Your Honor.

8 MR. RATHKE: Yes.

9 THE COURT: Okay.

10 (The jury entered the courtroom.)

11 THE COURT: Thank you. Please be seated.

12 Members of the jury, I just -- I haven't told you  
13 this, but we did talk about a stretch break, and you've had some  
14 stretch breaks, and I found that taking stretching breaks helps  
15 everybody stay awake and pay attention.

16 So when we do get to the witnesses, we have a rule  
17 called sequestration. It's Federal Rule of Evidence 615.  
18 Sequestration's a fancy word meaning that witnesses who are  
19 going to testify can't be in the courtroom to hear the other  
20 witnesses' testimony, and I think you can figure out the reason  
21 for that. We don't want witnesses to be influenced by what  
22 other witnesses testify to. And there are some exceptions.

23 So, for example, each side gets to have a  
24 representative, so the plaintiff has a representative from  
25 Security National Bank, and Abbott has a representative from the

1 corporation. And they may or may not testify. But other folks  
2 will be excluded once the opening statements and the trial  
3 actually begins.

4 So because it takes a moment or two for a witness to  
5 get off the witness box and leave and for a new one to come in,  
6 for me to swear them in, that's always a good time to take a  
7 stretch break. So I'll try and remind you for a while, but then  
8 you'll get in the habit. As soon as a witness steps down, you  
9 can automatically stand up and take a stretch break till that  
10 other witness is in the courtroom, I swear that witness in, the  
11 witness is seated. When the witness then is seated, then you  
12 can be seated, and that way you get some extra stretch breaks  
13 out of the deal.

14 So you should have on your chair the small phone book  
15 size set of jury instructions. I'm just kidding you. They're  
16 really not that long. And it says on it "Instructions to the  
17 Jury," and then it has what we call the caption. Every case has  
18 a caption. It's just the name of the case. It's a way that we  
19 keep track of our cases. So this is in the United States  
20 District Court for the Northern District of Iowa, Western  
21 Division, and the plaintiff, Security National Bank, Plaintiff,  
22 as Conservator for J.M.K., a minor child, Plaintiff, Abbott  
23 Laboratories, Defendant, says instructions to the jury. And  
24 then you'll see there's a table of contents. So at any time  
25 throughout the trial you want to look up one of the instructions

1 or think about it or take notes on it, you'll have a table of  
2 contents for you to do that.

3                   And then you flip the page, and you notice we have 20  
4 instructions, and then we have a verdict form. And a verdict  
5 form is simply how you record your verdict. But we'll go over  
6 that. So if you flip the next page, then it says number 1,  
7 introduction. And that would be the start of the jury  
8 instructions. I'm going to go over these with you.

9                   (The Court read instructions numbers 1 through 19 in  
10 open court.)

11                  THE COURT: But I would like you to turn to the page  
12 following 44. It's what we call the verdict form, and this is a  
13 three-page document that you'll fill out after you've concluded  
14 your deliberations and hopefully reached a unanimous verdict.  
15 I'm not going to read the whole verdict form, but I just want to  
16 kind of point out what it looks like because it's kind of a  
17 snapshot actually of the whole case.

18                  Question 1 -- Roman numeral 1, the conservator's  
19 claims, step 1, verdicts, and it just gives you an opportunity  
20 on who you rule for on the three claims, the conservator or  
21 Abbott. Then if you found in favor of the conservator on the  
22 warning claim, then you have an opportunity to check which of  
23 the warnings apply.

24                  And then step 2, if you found in favor of the  
25 conservator on one or more of the claims, you again have an

1 opportunity to fill out each form of damages that you've been  
2 instructed on. And then there's a place to total the  
3 compensatory damages.

4 And then step 3 is if you found for the conservator on  
5 either the design defect claim or the warning defect claim,  
6 there's an opportunity to put down punitive damages.

7 And then section 2 would be Abbott's specific  
8 defenses. And it's a question of whether or not they've proved  
9 the state of the art specific defense and then whether or not  
10 they've proved the intermediary specific defense, place for the  
11 date, foreperson will sign it, and the rest of the jurors.

12 Just so you know, the final instruction I give you  
13 just tells you that you need to elect one of you as the  
14 foreperson so that person can speak for you here in court.

15 So why doesn't everybody take a stretch break.

16 Please be seated, members of the jury.

17 Mr. Rathke, are you ready to proceed with the opening  
18 statement?

19 MR. RATHKE: I am, Your Honor.

20 THE COURT: Okay. Thank you.

21 MR. REIDY: Your Honor, could I have just a moment  
22 with Mr. Rathke?

23 THE COURT: You may.

24 MR. REIDY: Your Honor, we had an expert witness in  
25 the courtroom that should be excluded for the opening

1 statements.

2 THE COURT: Yeah. Wasn't that the understanding?

3 MR. RATHKE: I thought the understanding was from  
4 testimony, but she'll be happy to.

5 One thing that Judge Bennett said this morning really  
6 scared me. He said that we've got some really good lawyers  
7 here, and I hope during the course of the trial that I'll live  
8 up to his expectations and yours and present the evidence that  
9 you need to decide the case in a fair manner.

10 This story actually begins in 2001 when several babies  
11 in a Memphis hospital got meningitis, and some of them died.  
12 They determined that the bacteria that caused the meningitis was  
13 E. sakazakii. And they traced that bacteria to powdered infant  
14 formula that the hospital was providing for those infants.

15 Because of that very sad incident, the FDA determined  
16 that it would do a survey of all the manufacturing companies in  
17 the United States, you know, taking random cans of powdered  
18 infant formula and test them rigorously for E. sakazakii.  
19 Twenty-eight percent of the cans that were tested from all of  
20 the manufacturers contained some E. sakazakii.

21 There's a group called the International Formula  
22 Council which represents the companies. It's a trade  
23 association, and Abbott and the other companies are members.  
24 And they became very concerned about possible regulation which  
25 might occur due to this E. sak problem.

1                   But the IFC recognized the reality, and we have some  
2 of those internal documents that you'll see and read at least  
3 part of it. They recognized the reality, and so to quote one of  
4 the documents -- this is an IFC document -- under current FDA  
5 testing procedures, it is anticipated that E. sak will  
6 eventually be found in powdered infant formula made by all of  
7 the infant formula manufacturers. They also said in another  
8 memo although proactive measures may be taken to reduce the  
9 level and frequency and incidents of E. sak in powdered infant  
10 formula, total eradication of the microorganism from powdered  
11 infant formula appears unfeasible due to the nature of food  
12 powder manufacturing. And they also said in reporting on the  
13 extent of the problem they're having the published literature  
14 has reported that since 1988 about 10 percent of the powdered  
15 infant formula tested positive for E. sakazakii.

16                   So this is real. I'll bet you didn't know that. This  
17 is real. Powdered infant formula contains this bacteria  
18 E. sakazakii. The question is always how much, but it is there.  
19 And that's what this case is about. This isn't a case about  
20 power lines cause cancer, you know, junk science. This is  
21 science. Powdered infant formula contains E. sak. E. sak harms  
22 babies.

23                   Now, Judge Bennett explained to you the reason why we  
24 have the name of the case. The Security National Bank of Sioux  
25 City has been kind enough to act as conservator and bring this

1 claim on behalf of Jeanine, Jeanine Kunkel. We've been  
2 referring to her as J.F.K. or J.M.K. or something like that.  
3 Jeanine is the way I will refer to her because that's her name,  
4 and she's now five years old. She's severely disabled. She  
5 cannot walk. She cannot talk, and she never will. She's fed  
6 through a stomach tube and essentially frozen at the capacity of  
7 a five-month-old baby and will never go beyond that.

8 Now, how did this happen? How could this happen?  
9 Well, it happened because she got a horrible meningitis  
10 infection when she was nine days old from the powdered infant  
11 formula that she was fed which was contaminated with this  
12 bacteria called E. sakazakii. Abbott made this powdered infant  
13 formula. The name that it used for selling it is Similac which  
14 is a term that they use for all their formula. And this was  
15 called NeoSure.

16 NeoSure is a type of powdered infant formula that  
17 Abbott markets for babies under the age of 12 years -- or 12  
18 months old who were born prematurely, and they call it NeoSure.

19 The bank is bringing this lawsuit on Jeanine's behalf  
20 for making this contaminated powdered infant formula, for  
21 providing it to parents for babies who should not have been  
22 exposed to a product that could be contaminated with E. sak and  
23 for not warning parents and their doctors that powdered infant  
24 formula could be contaminated so that they could make an  
25 informed choice not to feed it to their babies who were so young

1 as to be susceptible to infection from E. sakazakii.

2 So what are you in for? Well, you're in for a biology  
3 lesson from a medical doctor and four Ph.D.s, lots of documents,  
4 not necessarily in order. You'll have a fair amount of prior  
5 testimony read to you. Doesn't sound very exciting, but the  
6 case is interesting. It involves bugs and babies.

7 Now, as we start this case, I can understand why you  
8 might be skeptical. You're looking at me and saying, "What? I  
9 never heard of this before. Why haven't I heard about this  
10 before? Isn't infant formula safe? Why would Abbott put a  
11 product on the market that could make babies sick?"

12 And I understand these feelings and the fact that many  
13 people think there's too many lawsuits. What I would like you  
14 to do is really listen to your common sense because that's what  
15 this case really comes down to, kind of a common sense, common  
16 sense for Abbott, common sense for the mom, common sense when  
17 you're listening to the experts.

18 And I think when you do, there may be too many  
19 frivolous lawsuits, but this ain't one of them.

20 There's some rules that companies that make powdered  
21 infant formula have to -- have to follow. They've got a  
22 responsibility to design a safe product. And by design, I mean  
23 in the large term. Who is the product intended for? Should  
24 this product, powdered infant formula, be designed for a baby  
25 who's under the age of 28 days?

1           They've got a responsibility to manufacture a safe  
2 product, and they agree that if their product contains E. sak  
3 that's a bad thing. They don't intend to have E. sak in their  
4 product. So they have a responsibility to manufacture a product  
5 that's safe and is E. sak free.

6           And they've got a responsibility to warn of serious  
7 risks so that doctors and parents can make an informed choice  
8 about this: Should we feed this newborn powdered infant  
9 formula, or should we instead feed this baby sterile,  
10 commercially sterile, ready-to-feed liquid formula, two  
11 products, which one should we -- we need enough information to  
12 be able to make that choice.

13           Now, the characters -- let me introduce you to the  
14 characters here, and things are going to come up just like magic  
15 on this screen behind me I hope. That's just to show you what  
16 the words look like. Enterobacter sakazakii. It will be  
17 referred to a number of ways. E. sakazakii is a very proper  
18 way. It has a nickname of E. sak. Sometimes it's referred to  
19 as ES.

20           It was first identified by 1980 -- around 1980 by  
21 Dr. Jim Farmer. You'll meet Dr. Farmer because he's one of our  
22 expert witnesses. He named it after a friend of his named  
23 Dr. Sakazakii and a fellow scientist. And yes, Dr. Sakazakii  
24 was honored to have this bacteria named after him.

25           Now, all living things are members of families.

1 You've probably heard that term. The family -- no, go back.  
2 The family is kind of hard to pronounce, but it's --  
3 enterobacteriaceae is how it's pronounced. It's often referred  
4 to as EB, and that's the family. It's got some cousins that you  
5 may be more familiar with: E. coli, salmonella. It's not a  
6 good family.

7 However, as if this wasn't complicated enough, they've  
8 changed the name. Next slide. In 2008 as they learned more  
9 about this bacteria, they reclassified it, and they now call it  
10 cronobacter, and there are seven species in the group of  
11 cronobacter, and they are C. sakazakii, and then there's six  
12 more. And these are important distinctions to make.  
13 C. sakazakii and E. sakazakii, however, we're all talking about  
14 the same thing.

15 So that's the -- that's the bug. That's the villain,  
16 and now I'll tell you about its ride. Its ride is powdered  
17 infant formula -- or is infant formula, and there's three types  
18 of formula. I don't know if you all know this, but just to make  
19 sure everybody's on the same page, there's the ready-to-feed,  
20 often abbreviated RTF, which is commercially sterile and liquid.  
21 And that is sold in bottles, and at the hospital it is in  
22 individual servings. And it's ready to feed to the infant.

23 The second is concentrates. I mention that just so  
24 you know it exists. It's also commercially sterile. And it's  
25 also liquid, but you do add water. It has nothing to do with

1 this case. It's just another type of formula.

2 And then the third is the powdered infant formula, and  
3 it is not sterile. It is not sterile. Even though many people  
4 assume that it is, it is not.

5 And then finally its destination, and these are some  
6 terms that will be thrown around, but they all have a very  
7 specific meaning. An infant is a baby less than 12 months old.  
8 A neonate -- and that's a term that's going to be used from time  
9 to time. A neonate is a -- set it back, Pat. Neonate is a baby  
10 that's less than 28 days old. And I think the judge in his  
11 instructions used the word newborn, and those terms newborn or  
12 neonate are synonymous in this case. Newborns, neonates, less  
13 than 28 days.

14 Then there's some special types of babies. There's  
15 premature. The line is 37 months (sic). And this baby was born  
16 at 37 months, so it's not premature but right on the line. And  
17 then low birth weight. Low birth weight is a baby who weighs at  
18 birth less than 2,500 grams or less than 5 1/2 pounds. Jeanine,  
19 when she was born, was born at 37 weeks and weighed 4 pounds, 14  
20 ounces, so she was a low-birth-weight -- low-birth-weight baby.  
21 So those are the characters.

22 Now, I'm going to tell you a little bit about some of  
23 the experts that are going to testify here on behalf of  
24 plaintiff.

25 One that we're going to start I hope, you know,

1 tomorrow will be the second witness, is Dr. Scott Donnelly.  
2 Dr. Scott Donnelly is a microbiologist who was employed by  
3 Wyeth -- that's W-y-e-t-h -- for many years, for 23 years. And  
4 beginning in 2001 when this Memphis outbreak took place, it was  
5 his job to keep E. sak out of the powdered infant formula that  
6 his company made.

7 He will explain to you how powdered infant formula is  
8 made, I mean, kind of a broad overview, not all the details.  
9 And he'll tell you that ingredients are all mixed into a liquid;  
10 okay? So you got a liquid which has all the ingredients, and  
11 then it's pasteurized, so all the bugs that are in this liquid  
12 are dead. Then it's dried. The dryer is a six-foot -- it's a  
13 huge building. It's six foot -- six stories tall, six stories  
14 tall. And when it starts at the top, it's liquid; and when it's  
15 at the bottom, it's powder. That's how they convert it. We are  
16 now in what he will call the dry phase. That's where  
17 contamination can occur. It's in the dry phase. The dry phase  
18 starts with the dryer and ends with the packaging.

19 He will tell you that the only way that you can keep  
20 E. sak out of your product is to keep your factory clean,  
21 rigorously clean, particularly that portion where the powder is  
22 in the dry phase. That's how you keep E. sak out of your  
23 powdered infant formula.

24 And he will testify -- he'll tell you that Abbott's  
25 procedure to control E. sak in its factory were deficient in

1 several respects. They wet cleaned and then they did not use a  
2 sanitary -- the sanitizing risk -- rinse.

3 They also went around and tested various portions of  
4 their factory to look for bacteria, particularly E. sak, and he  
5 will explain to you that the factory testing -- and it will  
6 often be referred to as the environmental testing, testing  
7 within the factory -- was deficient in a number of respects.

8 He will also tell you that the finished product  
9 testing was deficient and that both could give rise to false --  
10 false negatives. A false negative is when the testing says  
11 negative but that's not true.

12 The finished product -- when Abbott makes a batch of  
13 powder like this NeoSure, it's a hundred and fifty -- over  
14 150,000 pounds is made at one time. That's a batch. That's a  
15 lot of powder. That's tons and tons of powder. And what they  
16 test is about -- oh, it's a little less than two pounds. That's a  
17 what they test. And when -- if the test is negative, the  
18 product goes out the door and on to the market.

19 And he will tell you that that test is deficient in a  
20 number of respects, again leading to false positives -- or false  
21 negatives.

22 He will also testify that when you find E. sak in your  
23 factory it's a big deal or at least it ought to be, but it  
24 wasn't in Abbott. You see, Abbott found E. sak inside its plant  
25 the very day that the batch which was fed to Jeanine, the very

6 //. That's what they test. They say it's a  
7 good indicator. If it turns out it's negative, then they  
8 don't -- that satisfies them. That actually is invalid.

9                   But in this particular case when they were in the  
10        // drain, they did get a positive, several positives, on  
11        their // test.

12                   What they do then is they say, okay, now we're going  
13 to test for E. sak. We're going to actually look for the  
14 organism that we need to find. And guess what. That was  
15 positive too. They found and tested E. sak in their factory in  
16 the /////////////// drain the same day that Jeanine's powder was dried.

17                   Then they did something else. They took that -- you  
18 know, the testing is kind of like you might remember chemistry  
19 or biology where you put stuff into petri dishes and let them  
20 grow. That really is -- that's how they do it. And they grew  
21 88 colonies.

Well, they decided to send them for another test.

1 86 were not tested the second time. //  
2 // looked at them, says they're negative, and so Abbott  
3 said, okay, no problem here. That's what happened. The batch  
4 was then released to the market.

5 Another microbiologist who's the specialist in this  
6 testing named Catherine Donnelly will explain to you why the  
7 first test where they found the positive E. sak is more  
8 conclusive than the second test and how all of the cultures or  
9 at least most of them should have been //,  
10 tested and that the testing should have sent out bells and  
11 whistles.

12 And both Dr. Donnellys -- and they are husband and  
13 wife. Both Dr. Donnellys will tell you that if you get a  
14 positive test for a bacteria you're looking for like E. sak, a  
15 subsequent negative test does not wipe out the positive test.  
16 You still have a positive test, and you have to deal with it.  
17 It cannot be explained away by "we'll give it another test;  
18 turns out negative; no problem." But that's what Abbott did  
19 which brings us to Jeanine.

20 You see, the batch -- that batch made it all the way  
21 here to Sioux City. Abbott put it in a gift bag. And when the  
22 gift bag -- you know, as we've talked about a little this  
23 morning, gift bag is when the mom is discharged from the  
24 hospital after giving birth, they give a gift bag, and it's for  
25 promotional purposes. It has, you know, literature and free

1 stuff from the company.

2 And what do you know? In this gift bag given to  
3 Jeanine's mother was a can of powdered infant formula NeoSure  
4 and later ended up being fed to Jeanine because this case is all  
5 about Jeanine.

6 Jeanine, as I mentioned before, can't do anything.  
7 She needs 24/7 care. She was born a healthy baby on April 14,  
8 2008, in St. Luke's Hospital here in Sioux City. Her mother had  
9 had a previous child who is -- who gave birth cesarean. And so  
10 this was a scheduled hospital visit where it's scheduled, you  
11 come in this day, and we will do the C-section.

12 Jeanine was a twin, a fact that was known, of course,  
13 quite a bit before that, months earlier. And on April 14, Megan  
14 Surber, the mom, gave birth to her twins, Jeanine and James,  
15 Jeanine being small not because she was particularly premature  
16 although she was on the edge; simply because she was a twin.  
17 She was 4 pounds, 14 ounces. Her brother James was slightly  
18 heavier. But it was over 9 pounds of baby.

19 Jeanine was never breastfed. Her mother tried to  
20 breast-feed her baby, her firstborn, and was unable to do that.  
21 So that was contemplated that she would be formula fed.

22 And at the hospital she received NeoSure. The doctor  
23 felt that NeoSure was the appropriate type of formula because it  
24 is for premature babies, babies that need a boost of nutrient,  
25 and there's -- the doctor is absolutely right. NeoSure is

1 definitely the right product for a baby like Jeanine.

2 And so during the time that she was in the hospital  
3 she received NeoSure ready-to-feed in the single service --  
4 single serving containers. She was discharged with her mother  
5 at three days. And that's when she -- her mother received the  
6 gift bag. The gift bag contained, besides promotional material,  
7 a bottle of ready-to-feed, so more ready-to-feed and a bottle of  
8 powdered infant formula.

9 Jeanine was healthy for 10 days until April 24 when  
10 she developed meningitis, E. sak meningitis. And no one  
11 disputes that it's -- E. sak is the bacteria, you know, because  
12 they did the culture from Jeanine's body. They looked at it,  
13 identified it as E. sak. So no one questions that.

14 Our first witness will be Janine Jason, and she'll  
15 start this afternoon, and she'll explain to you that E. sak is  
16 pretty harmless to most humans. And humans where it's not  
17 harmless are newborns who have no bacteria in their gut to begin  
18 with and they don't have stomach acid and they really don't have  
19 much of an immune system at birth. And it's especially harmful  
20 to newborns who are premature or low birth weight or have  
21 immune -- problems with their immune system. If E. sak gets  
22 into their digestive tract, they have no defenses, no defenses.

23 The E. sak will -- it's -- the perfect environment for  
24 E. sak to grow is a baby's gut, and that's where it goes to town  
25 and eventually goes to their brain and literally takes out their

1 brain. It enters the -- but it enters the digestive system  
2 through the mouth, through the mouth. It goes into the  
3 digestive system, into the blood, into the brain.

4 And this isn't particularly controversial stuff. The  
5 World Health Organization and the entire scientific community  
6 agree -- and I'll read you a short statement in a 2004 WHO  
7 report, WHO being the World Health Organization. Amongst  
8 infants, those at greatest risk for *E. sakazakii* infection are  
9 neonates, particularly preterm infants, low-birth-weight  
10 infants, or immunocompromised infants. There's no one that  
11 disagrees with that statement.

12 As I said, Jeanine was born April 14. The events 10  
13 days later are particularly important, and we'll spend some time  
14 on that. But from birth until the evening of April 23, she was  
15 fed ready-to-feed, commercially sterile ready-to-feed. She got  
16 some of the single servings from the hospital which she used up.  
17 And then she took the bottle of ready-to-feed and used that up.  
18 And on April 23 she had used all of that up and was now turning  
19 to the can of powdered infant formula, NeoSure, that Abbott had  
20 given her in a gift bag.

21 And the first feeding was at nine o'clock in the  
22 evening. She had been fussy and crying a little earlier that  
23 evening but nothing in particular, and you'll learn that in the  
24 evenings that's when babies cry more than any other time of the  
25 day.

1                   She was fed at nine o'clock, went to sleep. At  
2 midnight she woke her mother because she was hungry, had her  
3 second bottle of powdered infant formula, and went to sleep. At  
4 a.m., she woke up, had her third bottle of powdered infant  
5 formula, and went to sleep.

6                   Then on -- some time -- and nobody's really watching  
7 the clock at this point. It's about maybe 6 a.m. on the morning  
8 of April 24, and Jeanine is getting fussy again, and the mom  
9 will describe that. Finally, you know, it's time for her  
10 feeding. Her mom gives her her fourth bottle of powdered infant  
11 formula, and this time Jeanine's not particularly interested and  
12 doesn't finish it.

13                  The mom checks her temperature, and she doesn't have a  
14 fever. And so the day goes on. And as the day goes on,  
15 Jeanine's condition worsens. She doesn't eat her subsequent  
16 feedings. By the afternoon she's developed a fever. Megan  
17 Surber takes her temperature and sees that she's feverish.  
18 Megan calls the doctor. Doctor says bring her into the clinic.  
19 The doctor meets her at the clinic and says let's take her right  
20 to St. Luke's Hospital. And that's when she is admitted. The  
21 diagnosis was neonatal E. sakazakii meningitis. She was two  
22 days later airlifted to Children's Hospital in Omaha.

23                  Dr. Jason will explain that Jeanine ate sufficient  
24 powdered infant formula to consume enough E. sak to cause an  
25 infection and that enough time had passed between her first

1 feeding and the onset of symptoms.

2 So how do we know the source of the E. sak was  
3 powdered infant formula, because that's really the question  
4 here? If it is, they're guilty, they're liable. If it's their  
5 powder -- if it's their E. sak, they've got no defense.

6 Well, first of all, it's the only thing she ate that  
7 wasn't sterile. Megan even boiled the water from her tap before  
8 she mixed that water with the formula. Everything that Jeanine  
9 Kunkel consumed prior to 9 p.m. on April 24 was sterile. The  
10 powdered infant formula, not the water, but the powdered infant  
11 formula was the first and only nonsterile thing that she  
12 consumed before getting sick. And her mom followed all of the  
13 instructions on the label and more. So that's one reason. It's  
14 the only thing she ate.

15 Second, there's the association, the epidemiological  
16 association, that everyone knows exists between E. sak and  
17 powdered infant formula. And when I say everyone knows, you  
18 didn't know it, a lot of people don't know it in the public, but  
19 the industry knew it. The industry knew it, and you'll see a  
20 lot of documents showing their knowledge of that fact.

21 The third is what I mentioned before, that their plant  
22 was contaminated with E. sak the very day this batch went  
23 through the dryer.

24 And then a fourth reason is this: Dr. Jason is not  
25 only a medical doctor, but she's also an epidemiologist trained

1 by the Centers of Disease Control. And she studied the  
2 approximately 100 cases that -- of E. sak infection in babies  
3 and saw that 90 percent of them -- the records demonstrate that  
4 90 percent of them and maybe more but 90 percent for sure were  
5 fed powdered infant formula. And this establishes an  
6 epidemiological link between powdered infant formula and E. sak.  
7 And this and the other factors led her to the firm conclusion  
8 that the source of E. sak infection was the powdered infant  
9 formula.

10 Now, Abbott doesn't agree. That's why we're here.  
11 Abbott says, well, our powdered infant formula's safe and poses  
12 no risk to babies. That's what it says. And it will point out  
13 to you that the CDC got ahold of the rest of the can that  
14 Jeanine was feeding from and tested it for E. sak and did not  
15 find any. The FDA went out and got 17 cans from that -- this  
16 huge batch which Abbott had created and tested those for E. sak  
17 and found none.

18 And the explanation for that is this, and this will  
19 come out and really not be contested. E. sak clumps. It's not  
20 uniform throughout a batch or even a can. It's here, and it's  
21 not here. It's not spread evenly. The clumps are microscopic  
22 and can't be seen by the naked eye. Remember it's pasturized  
23 and then dried, and in the factory powdered infant formula will  
24 become contaminated when it has contact with surfaces and  
25 areas -- or the powdered infant formula will become contacted

1 (sic) when it has contact with E. sak in the surfaces or areas  
2 that it's in.

3                   And this has happened in other cases where the other  
4 tests after the child gets ill turn out to be negative. And  
5 scientists at the CDC agree. But that doesn't mean that the  
6 powdered infant formula doesn't cause it. What it means in a  
7 sense is that a baby ate the evidence.

8                   Through its IFC, the industry resisted -- and you'll  
9 see this -- all efforts to warn parents that powdered infant  
10 formula is not sterile. Now, by 2008 the cans did say it was  
11 not sterile in real fine print. So the industry eventually  
12 voluntarily provided that information to parents. But they  
13 continue to oppose informing parents that powdered infant  
14 formula may contain E. sak. In other words, they say it's  
15 sterile (sic), but they don't say what it -- what the problem  
16 is. They don't say what the risk is. They say don't -- be sure  
17 to follow our instructions in making it, but they don't explain  
18 that there's a bacteria that may be present. And they don't  
19 explain that this risk is greater for neonates and particularly  
20 those neonates that are premature or low birth weight.

21                   In fact, Abbott makes a formula just for them, a  
22 powdered infant formula just for them. Nothing's wrong with  
23 their making the ready-to-feed NeoSure. It's a fine product and  
24 perfectly safe. Why they make it in powder is hard to explain.  
25 Abbott -- but it continues to market powdered infant formula

1 even though it sells a perfectly safe alternative, the NeoSure  
2 ready-to-feed.

3 Abbott's going to point the finger. Abbott says not  
4 us, not us. It must be them, them, them, them. Abbott blames  
5 and points the finger at the mom, the dad, the older half  
6 brother, all the relatives or friends who might have held the  
7 baby, the kitchen, the food in the refrigerator, the family dog,  
8 the city water. They even point the finger at the doctor and  
9 say, "Why didn't you tell the mom that our product is unsafe?"  
10 Talk about corporate responsibility. And I haven't even  
11 named -- you won't believe the long list of other things that  
12 may have caused this.

13 Trouble is -- for Abbott is that there's no scientific  
14 evidence, none, to support it. Iowa health authorities went to  
15 the home and tested for E. sak in the kitchen and did not find  
16 any. Moreover, not one single case has ever existed of E. sak  
17 infection in babies in which there's been -- it has been proved  
18 that the cause was anything other than powdered infant formula,  
19 not one. And it makes no sense. If babies got E. sak infection  
20 from everything under the sun, there'd be a lot more cases.  
21 Babies would be dropping like flies.

22 James, the twin brother, stayed at the hospital for  
23 ten days because of some unrelated health problems he had. He  
24 came home on April 24, the same day that Jeanine went to the  
25 hospital. Jeanine -- or James was in the same environment.

1       Same relatives were holding him, same dog.

2           But there's two things different about James. One is  
3       by the time -- he got his gift bag too, of course. By the time  
4       they had run out or were getting -- you know, they fed him the  
5       ready-to-feed first and by the -- and while they were feeding  
6       him the ready-to-feed, they found out -- you know, that's when  
7       Jeanine got sick and was diagnosed and the family understood  
8       that powdered infant formula is associated. They never fed  
9       James powdered infant formula. He never got powdered infant  
10      formula. So that's kind of its own little study. Jeanine got  
11      powdered infant formula and developed an E. sak infection living  
12      in the same house, same relatives. James did not get powdered  
13      infant formula, got only the ready-to-feed. And guess what. He  
14      never got sick.

15           And un -- and unfortunately, the FDA, even though they  
16      went -- through the Iowa health authorities went to Megan's  
17      house, they never went to Abbott, they never went -- said we  
18      want to inspect your plant, we want to test your plant, we want  
19      to see if we can find E. sak in your plant. That never  
20      happened. They didn't even ask for records that would tell them  
21      what kind of environmental testing results occurred during the  
22      time that this batch was made. That was never done.

23           If they had, they'd have found out about the ///  
24      drains, but they never did find out about the /// drains, so  
25      no official cause was ever determined. And since it could not

1 be certain, nothing happened, there was no recall, and Megan has  
2 a sick baby.

3                 Although science demands certainty, in a civil lawsuit  
4 and in actually most things in human affairs, absolute  
5 certainty's pretty hard to find. And the law doesn't require  
6 it. And keep in mind, you know, a bunch of lawyers have been up  
7 here balancing scales. The question to you, for you will be is  
8 it more true that the powdered infant formula was the source of  
9 the E. sak than any other source or all the other sources put  
10 together?

11                 So we're at the beginning of the case, and I've  
12 talked -- I'm probably close to 30 minutes. At the end of the  
13 trial I'm going to ask you to reach the only true, logical  
14 conclusion that Abbott's powdered infant formula was the source  
15 and that we have proved it more likely than not. Thank you.

16                 THE COURT: Members of the jury, it's 10 minutes to 3.  
17 We'll be in recess until 3:15. Thank you. And then we'll come  
18 back and hear the defense opening.

19                 (The jury exited the courtroom.)

20                 THE COURT: Anything we need to take up, counsel?

21                 MR. REIDY: Nothing from us, Your Honor.

22                 THE COURT: Okay. Thanks.

23                 (Recess at 2:53 p.m.)

24                 THE COURT: Ready to have the jurors brought in?

25                 MR. RATHKE: Yes, Your Honor.

1                   MR. REIDY: Yes, Your Honor.

2                   (The jury entered the courtroom.)

3                   THE COURT: Thank you. Please be seated.

4                   Mr. Reidy, any time you're ready.

5                   MR. REIDY: Thank you, Your Honor. Ladies and  
6 gentlemen, I want to take up the circumstances described in 2001  
7 in Mr. Rathke's opening just to clarify a few things as to what  
8 the proof will show.

9                   This is the Memphis Portagen outbreak of 2001. And in  
10 that thing, even though it was not several meningitises -- it  
11 was only one, and it was not some deaths; it was just one  
12 death -- it was obviously a very serious incident, and there  
13 were a number of children who were colonized with E. sak, and  
14 so they -- and it was traced back to the powdered infant formula  
15 there.

16                   But I want to make sure that you understand that the  
17 proof is going to show that with respect to that instant the  
18 powdered infant formula, of course, was not Abbott's and also  
19 that the proof will show with respect to the testing that he  
20 talked about where he said 28 percent of subsequent testing,  
21 they found it in 28 percent of powdered infant formula samples,  
22 it was actually 23 percent which is not too important. But it  
23 may be important that none of it was Abbott's, and all the  
24 product was recalled from all the manufacturers who were found  
25 to be positive in that study. And, of course, none of Abbott's

1 was recalled at that time.

2           This is not a case about whether or not powdered  
3 infant formula manufactured by somebody else at some other time  
4 has or can cause E. sak meningitis infections. It's a case  
5 about whether or not this can of powdered infant formula that  
6 Jeanine Kunkel had three servings from caused her meningitis  
7 E. sak, and that's what the proof will be about.

8           We will talk to you about Abbott's state of the art  
9 manufacturing plant, and we'll have a witness, Sharon Bottock,  
10 the quality assurance manager from there, tell you about how it  
11 works and how things are put together there and how Abbott works  
12 to be sure that they have a methodology of both careful  
13 manufacture and careful testing to make sure that they don't put  
14 powdered infant formula on the streets or for sale that has  
15 contamination by E. sak or, for that matter, contamination by a  
16 number of other pathogens.

17           Pathogens are, of course -- you know, can be  
18 salmonella. There can be other ones that you have to worry  
19 about, so they have to worry about all those, although we'll be  
20 talking about E. sak in this case.

21           And she'll tell you how Abbott is dedicated to  
22 providing a safe environment for the manufacture of powdered  
23 infant formula so that when it leaves Abbott's process it's been  
24 both manufactured correctly and then even though manufactured to  
25 the state of the art then tested to state of the art so that if

1 there is any E. sak in the powdered infant formula it is caught  
2 before it gets out for publication or before use. And that will  
3 be shown to you.

4 She'll describe the man -- the way it's manufactured,  
5 and it's manufactured in what's called a closed system. Once it  
6 enters the system, it's -- it basically is inside pipes and  
7 tubes until it comes all the way down to the dryer. And so it  
8 goes through that system all the way through. It's an extremely  
9 hygienic system. There's all kinds of cleaning done. Cleaning  
10 is done in place. The cleaning that's done is appropriate.  
11 You'll hear experts take on various battles about that, but it's  
12 a highly mechanized process. It's meant to minimize the amount  
13 of individual contact with the powdered infant formula.

14 //  
15 //  
16 //,  
17 //,  
18 and it's a highly mechanized, very state-of-the-art process done  
19 in very clean places and even isolated from the rooms in which  
20 it's in by and large so that it processes through in a tube. It  
21 comes through wherever it is in whatever process it can be so  
22 that it's kept as much as possible in a closed system.

23 I do need to talk about these presumptive positives in  
24 the drain, and you'll hear about that in great detail. And  
25 you'll see that there's just straight-up disagreement.

1                   The first thing I want to make sure you understand  
2 from the facts is that the drain is not in the dryer system  
3 itself. It's in a room in which the dryer system passes  
4 through. I described for you how the system is generally closed  
5 with -- it passes through various rooms. There is a drain. And  
6 Abbott conducts extensive environmental testing. They test all  
7 kinds of things. They test things that are far, far away from  
8 the production. They certainly test things that are outside of  
9 this closed system. The idea is to really be on top of this  
10 possibility of E. sak and to really test as much as you can.

11                  So even though the likelihood that a drain in a floor  
12 in a room with a system passing through it that is essentially  
13 closed to the environment that it's in could contain something  
14 so that they go down there and test it and take swabs in there,  
15 they do that because they're dedicated to making sure that  
16 E. sak doesn't have any chance to get into their stuff and, if  
17 it gets in there, that their testing finds it. And that's why  
18 they were down there swabbing this drain, not because it was  
19 actually part of the system in which the powder comes in  
20 contact. It's not.

21                  With respect to the way that works is they do a test.  
22                  ||||||||||||||||||||||||||||||||||||||||||||  
23                  ||||||||||||||||||||||||, And you'll hear about this.  
24 And they do that. And that will give you information as to  
25 whether or not it belongs to this family of cronobacters and

1 with respect to whether it belongs to that -- or the family of  
2 these bacteria.

3                   And with respect to whether it belongs to that, you  
4 get a -- this looks at some of the DNA.   ||||||||||||||||||||||||  
5   ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||  
6   ||||||||||||||||||||||||||||||||||||||||||||||||||||||||  
7   it, it registers a presumptive positive.

8                   Abbott's procedure which follows what the FDA  
9 recommends is they then have their -- that test is then  
10   ||||||||||||||||||||||||||||||||||||||||||||||||||||  
11   |||||||||||||||||||| because that's what the FDA recommends,  
12   ||||||||||||||||||||||||||||||||||||||||||||||||  
13   |||||||||| And the |||||| then does a much more  
14   extensive look at the DNA, and it comes up with a conclusion as  
15   to whether or not you're dealing with E. sak or not.

16                   And with respect to the stuff that was down in the  
17 drain inside the room with the system passing through it, it  
18 determined that that stuff was not E. sak.

19                   So the first sort of area of debate that you're  
20 hearing about in this prediction by the lawyers as to what the  
21 proof is is that even though we're only talking about something  
22 in a drain environmentally tested not inside the system in which  
23 the powder exists, that as to what was in that drain, this  
24   |||||||||| test |||||||||||||||||| was clearly negative  
25 for E. sak. So it was a bug, but it was not E. sak.

1                   And on our part, our expert, Dr. Martin Wiedmann from  
2 Cornell University, will explain to you how this presumptive  
3 positive works, what it means, what the ////////////// testing  
4 means, how it works, and why after the ////////////// testing is  
5 done Abbott can conclusively conclude and state that it was not  
6 E. sak even in the drain in the room through which the system of  
7 manufacture processed.

8                   The FDA conducts examinations of Abbott's  
9 manufacturing plant every year. They come out and take a look  
10 at it, make sure that it's up to snuff, and you'll hear about  
11 that during the course of the proof. We'll have that talked  
12 about as well.

13                   And Abbott also has a third party who comes in, a  
14 scientific group that comes in, and also inspects their  
15 processes for safety and for quality and goes through  
16 everything. They also go out to the plant at Casa Grande,  
17 Arizona, which is where this can was manufactured, and they look  
18 through everything there as well.

19                   Abbott's very concerned that the products that come  
20 out are healthy and safe and that they don't cause illness, that  
21 they help people avoid illness. NeoSure is a product that's  
22 meant to help premature and low-birth-weight babies do well and  
23 get back to full weight. And so obviously they are extremely  
24 concerned that it not contain a bacteria which can actually  
25 cause great harm to the baby, and they work really hard to make

1 sure that doesn't happen, and you'll hear all about that.

2 The other part that I want to talk to you about, the  
3 proof that you'll see, is the testing. And I want to talk about  
4 the testing, particularly related to this batch, and that is the  
5 batch from which the one can from which the three feedings that  
6 were given to Jeanine Kunkel came from, and so it's produced in  
7 a large batch. The batch probably -- you know, it's a  
8 commercial size batch. But they have regularly s -- regularly  
9 specified testing with respect to that.

10 So there's two -- two points of testing that I'll talk  
11 to you about briefly. One is the regular testing that's meant  
12 to make sure that no product gets out of Abbott's plant with  
13 E. sak in it.

14 And the second part of the testing is the specific  
15 testing that was done once Jeanine Kunkel was diagnosed as  
16 having E. sak meningitis and it was known that she had consumed  
17 some Abbott powdered infant formula. Then there was a bunch  
18 more testing both by Abbott and other people, and we'll have a  
19 lot of proof about that, and I'll summarize some of it, what I  
20 predict you'll see right now.

21 So put up slide 2.

22 Now, you don't need to figure these documents out, and  
23 we'll get it up in a second. I think the blackout might be on.  
24 We'll get these -- you don't need to spend time looking at the  
25 underlying documents here or trying to figure out what's in the

1 background. The point in this case is that Abbott has finished  
2 product testing that it did on this batch.

3 Now, this batch actually has two numbers associated  
4 with it. And you'll see that it has the RE00 number at the top  
5 of the call-out there and the RE10 number at the bottom of the  
6 call-out. And those two numbers are assigned to this single  
7 production batch because some of this product was going to  
8 Canada. And if they change it where there's going to be some to  
9 Canada and some to the U.S., they take the one production batch,  
10 and they give it two different batch numbers.

11 In this case that also resulted because of the  
12 protocols that they follow. Once they change a batch number,  
13 they have to put it through testing so that the normal testing  
14 of ////////////// was actually -- in this batch, this batch was tested  
15 for //////////////, so there was E. sak and other pathogen testing done  
16 on //////////////, twice the normal amount with respect to this  
17 particular batch.

18 And in all the testing that was done preshipment, the  
19 E. sak was negative as you see in those two call-outs.

20 Let's go to the next one. So then the next one -- and  
21 Mr. Rathke made reference to this which is slide 3 -- I want to  
22 make sure the right one's up. Apparently we're having some  
23 technical difficulty. Later when I'm operating it you'll see  
24 real technical difficulty.

25 Okay. Slide number 3. And again, you don't have to

1 look beyond the documents at this time because you'll get a  
2 chance to see these documents in detail during some of the  
3 testimony that occurs in the case. But this is the CDC testing  
4 of the can, so the Center for Disease Control which is obviously  
5 interested in outbreaks of disease such as if there could be an  
6 E. sak outbreak because of a contaminated shipment of a  
7 manufacturer's powdered infant formula, the Center for Disease  
8 Control came out and took a look at the can. And, of course,  
9 they tested it, and it was negative, and they did the testing  
10 they felt was appropriate to figure out whether it was in there  
11 or not.

12                   In addition to that -- you can move to the next  
13 slide -- the FDA came out, and they went to the hospital. The  
14 hospital had gotten four cases of NeoSure. There's six cans in  
15 a case. So the FDA pulled all the other cans that were in  
16 there, and they tested 17 cans. 16 of those cans were -- came  
17 off the line within 120 seconds or in the same 120-second period  
18 I should say as the can manufactured that Jeanine Kunkel used.  
19 So each one of these cans gets a minute put on it. It gets the  
20 date, the hour, and the minute put on it as it comes through the  
21 production line because if there is a problem, they want to be  
22 able to identify where in the line there is a problem.

23                   And in this case because the hospital shipment had  
24 probably gone to the boxes together, 16 of the 17 cans came out  
25 within the same 2-minute period as the can that Jeanine Kunkel

1 ate from. And so those were all tested by the FDA, and as you  
2 know, the FDA is charged with responsibility for making sure  
3 that there's no products on the market that are adulterated.  
4 They have the power to make recalls. They looked at this can.  
5 They looked at 16 of these cans, and they tested them, and there  
6 was no sign of E. sak. It was also negative for that.

7 Next, please.

8 And the final specific test of this batch that I want  
9 to talk to you about or an element of this batch is that as  
10 Abbott makes a batch and ships all the cans associated with the  
11 batch, they keep what's called a library sample, so they keep a  
12 library sample from each batch.

13 And after they learned of the breakout -- or I'm  
14 sorry, the breakout. After they learned that Jeanine Kunkel  
15 indicated that she had E. sak meningitis and had ingested their  
16 formula, they then went back to their library and tested it, and  
17 as you see under the number 1 there, it also was negative.

18 So this is an excessive bit of testing, and it's  
19 summarized in slide 6 where //////////////, twice the usual amount of  
20 the batch, are tested in Abbott, all of them negative. The CDC  
21 you'll see in the proof tested the very can, and it was  
22 negative. FDA tested 17 cans of formula, 16 of which came out  
23 in the same 2-minute period as the Jeanine Kunkel can, and then  
24 Abbott went back and tested its library batch. Every single one  
25 of those was negative for E. sak.

1           In addition to that, because the FDA did not feel that  
2 there was indication that the powdered infant formula was the  
3 source of the infection, there was no recall. There was no  
4 diminishment of the amount of the sales. So this batch contains  
5 hundreds of -- 100 -- about 100,000 cans which, depending on the  
6 size of the feedings, whether it's a 2-ounce feeding like  
7 Jeanine Kunkel was getting at the time or up to a 6-ounce  
8 feeding which might be -- it's between a million and four  
9 million feedings. So none of those were recalled off the  
10 market. Those feedings occurred out there, and there were no  
11 other reports of E. sak meningitis from that entire batch.

12           Abbott in its testing also went back and did finished  
13 product testing for three batches made before and after, three  
14 batches before and after this batch was made just to make sure  
15 that there wasn't some problem with the system, make doubly sure  
16 that there wasn't a contamination. So they went back and tested  
17 other batches.

18           Now, you'll see that the evidence is clear that the  
19 FDA and the CDC are very vigilant since the 2001 outbreak where  
20 the one meningitis death occurred and several other children  
21 were found to be colonized in a single intensive care unit down  
22 in Tennessee. The FDA and the CDC really jump on these things  
23 whenever there's a report of E. sak meningitis and infant  
24 formula's involved.

25           And so they were all over this, and the evidence will

1 show that FDA experts don't agree that it had to be the formula  
2 which is what the plaintiff's experts are going to tell you, had  
3 to be the formula, it's always the formula when it -- and then  
4 it goes. And you'll see what the evidence is on that as it  
5 comes in. I don't think that will hold up. But clearly the FDA  
6 does not agree with that, and you'll see that evidence.

7 So Abbott's -- you know, other reasons why it's fair  
8 that we think the proof will cause you to conclude and the  
9 evidence will show you is that Abbott's never had a recall of a  
10 PIF product for E. sak that reached the U.S. market. So it's  
11 never had a product on the U.S. market with E. sak in it that it  
12 had to recall, and E. sak has never been found in any sealed can  
13 of Abbott's PIF on the U.S. market ever. So they've never found  
14 it anywhere in a sealed can. I say sealed can because sometimes  
15 if the can is open in the home and there's contamination there,  
16 it can cross-contaminate if there's contamination inside the  
17 home. In this case it didn't cross-contaminate into the can,  
18 but it's never been found in a sealed can which is the way of  
19 establishing whether it came from Abbott.

20 Now, I do need to talk about non-PIF sources of  
21 E. sak, and I will talk about it. But what I want to make sure  
22 I make clear is that I'm not doing and neither is Abbott doing  
23 what was said in the opening of Mr. Rathke which is blaming  
24 somebody else for this. This is not blame the mother or blame  
25 anybody else.

1           It is very important from a scientific standpoint that  
2 we do talk to you about what the evidence will show with respect  
3 to where E. sak has been found, where it can be inside the home  
4 so that you have an idea of what the various risks are of where  
5 the E. sak came from in this case. So we're not trying to blame  
6 anybody with respect to this. What we're trying to make clear  
7 is that it wasn't Abbott's can that did it; and, therefore, the  
8 question is, okay, are there other places it could have come  
9 from. And so that's why we talk about these other sources.

10           So it does exist widely in the environment. You know,  
11 some of the scientific literature talks about it being, you  
12 know, essentially everywhere. It's been in soil, water,  
13 vegetation, meats, poultry, cereal, spices just to name a few of  
14 the foods. It's routinely found in home and hospital  
15 environments. Sometimes it's found in sinks, on bottle  
16 scrubbers, dust contents. It's not about just what the baby  
17 eats. That's not what's the case because many things that the  
18 baby eats also come into contact with the environment. Nipples  
19 come in contact with the environment. Bottles in which the  
20 formula's developed come in contact with the environment. The  
21 baby him or herself comes in contact with the environment,  
22 touching clothing, being touched by others, you know, being  
23 around other people who are infected.

24           E. sak is not something that only comes from powdered  
25 infant formula. E. sak infections occur in adults who clearly

1 are not eating powdered infant formula. E. sak occurs in  
2 infants who have not been fed powdered infant formula. So not  
3 every infant who has E. sak has -- or who -- has had powdered  
4 infant formula. Lot of people who get E. sak infections don't  
5 get meningitis because they're an adult, but E. sak infections  
6 come in the environment, and that's be -- they don't get it from  
7 powdered infant formula. They have to get it from all these  
8 places.

9           In humans you can find E. sak in catheters, feeding  
10 tubes, sputum. Pneumonia patients produce E. sak in some cases,  
11 IV lines, stethoscopes, and there's more reported cases of  
12 E. sak infection. You could encounter E. sak tomorrow. You  
13 might not even get sick. You could encounter a colony. It  
14 could enter your body. You might not get sick, just depending  
15 on how it affected you because you're an adult and everything  
16 else.

17           But of cases where people get sick and where they go  
18 in and they find out what bacteria is specifically making them  
19 sick as opposed to just giving them a broad-based antibiotic and  
20 sending them home knowing it will probably kill whatever  
21 bacteria it is, but where they actually define whatever it is,  
22 there's many more adults who are identified as having E. sak  
23 infections despite their lack of contact with powdered infant  
24 formula than there are children.

25           So let's put up number 7 which is up there already.

1 And that's just a list of various sources in the literature  
2 where it can be found. Has nothing to do with blaming anybody.

3                   With respect to the home -- and again, no blame  
4 associated with this -- there's a lot of areas in the home that  
5 weren't tested, and so we put up the various areas in the home  
6 and which ones were tested and which ones were not. Just go  
7 ahead and put it up, fill it in.

8                   So there was some limited testing done eight days  
9 after Jeanine Kunkel went in the hospital. At the home they did  
10 test the two areas next to the sink and the aerator in the sink,  
11 but the many other areas in a home where you could actually have  
12 E. sak occurring, not through any fault of anybody and not for  
13 anybody to be blamed, you know, homes are not sterile no matter  
14 what we do to them, no matter how clean we are. They're not  
15 sterile. Sterile is a really tough standard. Not even  
16 commercially sterile, they're not sterile at all. You know,  
17 people track things in. Dogs and pets track things in. People  
18 can also carry E. sak bacteria in their hands, their feet --  
19 doesn't have to affect them -- their clothing. You know, quite  
20 a few people had contact with Jeanine Kunkel at the hospital.  
21 They had contact with her after she came home.

22                   At the same time as Jeanine became ill at home, her  
23 father was very ill. In fact, he went to the hospital on the  
24 day after she was admitted, and he had been sick for some time  
25 and sick with pneumonia. And so he went into the hospital at

1 the same time. And so there's illness in the home at the very  
2 time.

3 The food we use isn't sterile. Refrigerators aren't  
4 sterile. She was drinking out of ready-made formula that was  
5 being kept in the refrigerator, a 32-ounce bottle. She was  
6 drinking two ounces at a time, so there were bottles that were  
7 around for periods of time, used, taken out, put on the  
8 countertop, used, put back in. You know, there's all kinds of  
9 possibility of cross-contamination.

10 Now, the CDC did test a couple of areas but -- and  
11 they did not find E. sak in the home eight days after the test  
12 was done. But it is important to note that there's -- just like  
13 everybody's home, there's bacteria in the home. They have  
14 several cultures, not E. sak, of bacteria that they list as too  
15 numerous to count. They don't give a value to it because when  
16 they test the home, obviously there's things that can be in the  
17 home and probably would be in my home as well.

18 Now, Abbott's pediatric infectious disease expert,  
19 Dr. Shulman, who's been head of the division of pediatric  
20 infection dis -- infection and disease at Lurie Children's  
21 Memorial Hospital and is the hospital epidemiologist, the guy  
22 who's charged in the hospital of figuring out where any bugs  
23 come from within the hospital, he'll testify that you don't have  
24 to eat bacteria, that this concept that it only comes in through  
25 the mouth which it might have and it could have come from

1 sources other than the powdered infant formula, but, in fact, it  
2 could come into the body in numerous ways, through any of our  
3 what's called mucosal openings which include obviously your  
4 eyes, nose, mouth, and any opening you might have in the skin.  
5 It can even be breathed. It can be aerosolized by vacuuming or  
6 by somebody running a hose or a sharp -- fast water flow, and it  
7 can come up into the air.

8                   And as I say, infants who've not had any powdered  
9 infant formula and adults who have had no powdered infant  
10 formula get E. sak-based infections, and they get it from the  
11 environment, so we know it is in the environment. It's simply  
12 not the case that if a baby who's fed powdered infant formula  
13 gets E. sak it has to have come from the powdered infant  
14 formula.

15                   There's another reason why the proof will show that  
16 the -- none of the three feedings over about six and a half or  
17 seven hours that Jeanine Kunkel had from a powdered infant  
18 formula can caused her E. sak infection. And Dr. Shulman, the  
19 fellow from Children's Hospital, Lurie Hospital, in Chicago will  
20 testify that it takes time after bacteria enters any person,  
21 even an infant, before it can cause symptoms and infection,  
22 before it can cause infection enough to the point where there  
23 are symptoms.

24                   And in his expert medical opinion -- you'll hear him  
25 say this -- the medical records in this case and includes the

1 statements of how the baby was doing made to the medical  
2 personnel at the time the family brought the baby in, that the  
3 medical records in this case will show that Jeanine Kunkel was  
4 already showing symptoms of the meningitis infection that she  
5 had at the time she received her first feeding from powdered  
6 infant formula.

7                   Remember as Mr. Rathke told you she came home on the  
8 17th. She went back into the hospital on the 24th. During that  
9 week she received feedings from liquid formula. Remember I've  
10 described the -- sometimes I think she had some ready-to-feed  
11 and then she had quart bottles, 32-ounce ready-to-feed which you  
12 would use for 2-ounce feedings, put it back in the refrigerator,  
13 do whatever one normally does with those things.

14                   And what Dr. Shulman will tell you is how ever the  
15 infection got into her, how ever it happened, it was already  
16 manifesting system -- symptoms at the time that she received her  
17 first feeding of powdered infant formula because she only gets  
18 her first feeding of powdered infant formula on the night before  
19 she goes into the hospital. He'll describe for you the medical  
20 and biological reasons why given the progression of symptoms the  
21 Abbott powdered infant formula which is just her last three  
22 feedings couldn't have been the source of her meningitis  
23 infection.

24                   I'm going to talk briefly about the label because this  
25 case features most importantly the question whether or not there

1 was E. sak in the powdered infant formula that she received  
2 which caused her illness.

3                   But put the label up if you would. Good.

4                   And this will be discussed at length during the trial  
5 because there is a specific warning claim. Most importantly as  
6 you've already heard, it comes into play if and only if there  
7 was E. sak in the powdered infant formula that she consumes.

8 Then you look at the label to see whether it's fairly warned for  
9 or not.

10                  But with respect to this, the most important thing to  
11 note about this is that the label does say at the very top --  
12 the first thing it says is that it's only to be used under the  
13 supervision of a doctor. There's a couple of other places where  
14 it says consult your doctor. It does say in that first  
15 paragraph over on the left -- and I'm not asking you to find it,  
16 but it does say that the product is not sterile, and then it  
17 provides instructions for how to prepare the product.

18                  In this case Dr. Beck who was the pediatrician who  
19 Megan Surber was using for her daughter Jeanine did, in fact,  
20 order or indicate that NeoSure should be used. And he didn't  
21 specify whether it should be NeoSure powder or NeoSure liquid,  
22 and I think the evidence will be he didn't care, he didn't  
23 distinguish between the two as creating risk or more safety and  
24 so that he ordered it and so that it was under his care that  
25 that was ordered.

1                   Now, the FDA regulates powdered infant formula labels.  
2 And Abbott's label exceeds -- you know, meets or exceeds the  
3 requirements that the FDA have for a label. They add some  
4 things that the FDA doesn't even require for its label. And  
5 you'll hear from warning experts about whether it makes sense to  
6 have really dire warnings about things on labels if, in fact,  
7 the risk is very, very small, et cetera. And so you'll hear all  
8 about that.

9                   But again, even with respect to the labeling claim, it  
10 starts with was there E. sak in the powdered infant formula that  
11 Jeanine received.

12                  So we do have a couple of affirmative defenses that  
13 we'll be talking to you about. And again, those two only --  
14 they only come into play again if you find that there was  
15 powdered infant formula, so we won't be spending a lot of  
16 time on -- I'm sorry, if you find that there was E. sak in the  
17 powdered infant formula that Abbott shipped, and so we won't be  
18 spending a lot of time on that for sure, but you will hear about  
19 it. And they basically are that the Abbott production facility  
20 was state of the art, that it was a state of the art production  
21 facility, that both the way they produced it, the way they  
22 tested for it, and the design of the system was state of the  
23 art, was the -- you know, as good as you can do with respect to  
24 making it.

25                  Now, you know, you can always test more, you can

1 always do more things, but state of the art has a certain  
2 meaning. Some of you will be familiar with it. And Abbott's  
3 plant was state of the art, and there will be expert testimony  
4 to that effect.

5                   And the other one is that there was a learned  
6 intermediary in that Dr. Beck said go ahead and use NeoSure and  
7 did not specify or care whether or not it was powdered or not,  
8 and so he was well aware of the circumstance with respect to  
9 the -- how children, if they consume anything that has E. sak in  
10 it, can get an E. sak infection. He was well aware of that, and  
11 yet he prescribed this. And so there's a learned intermediary  
12 defense that you'll hear.

13                  I'm not going to talk to you about the damages in the  
14 case other than just ask you that during that part of the case  
15 pay attention to it and, you know, take your eye to what's being  
16 claimed there. I don't think we're going to get to that if I'm  
17 right about what the proof shows as to whether or not there was  
18 contamination in the powdered infant formula.

19                  So when we finish the evidence -- and the evidence is  
20 what matters -- the Court's told you that what Mr. Rathke and I  
21 say here is nothing more than lawyers' predictions as to what  
22 something might be, and that's certainly true. But when we're  
23 done and the evidence is in, I'm going to come back here, and  
24 I'm going to tell you that I think the evidence came in pretty  
25 much the way I said it would, that the evidence, in fact, does

1 not establish in any way, shape, or form by a preponderance or  
2 any other standard that there was E. sak bacteria in Abbott's  
3 powdered infant formula that Jeanine Kunkel received. It will  
4 not show that, and I'll come back and talk to you then and ask  
5 you for a verdict for the defendant, Abbott. Thanks very much  
6 for your attention.

7 THE COURT: Okay. Why doesn't everybody take a  
8 stretch break, and then we'll start in with plaintiff's first  
9 witness.

10 Mr. Rathke, ready to call your first witness?

11 MR. RATHKE: I am, Your Honor.

12 THE COURT: Okay. Who would that be?

13 MR. RATHKE: That would be Dr. Janine Jason.

14 THE COURT: Good afternoon. If you'd just raise your  
15 right hand.

16 JANINE JASON, PLAINTIFF'S WITNESS, SWORN

17 THE COURT: Thank you. Please be seated. You can  
18 adjust the chair and the microphones so you can speak directly  
19 into them. And would you state your name, please, and spell  
20 your last name.

21 THE WITNESS: Sure. Janine Jason, J-a-s-o-n.

22 THE COURT: Thank you.

23 Mr. Rathke?

24 DIRECT EXAMINATION

25 BY MR. RATHKE:

1 Q. Would you state your name again one more time into the  
2 microphone.

3 A. Janine Jason.

4 Q. And how do you spell Janine?

5 A. J-a-n-i-n-e.

6 Q. And how do you spell Jason?

7 A. J-a-s-o-n.

8 Q. Where do you live?

9 A. South Carolina.

10 Q. And where in South Carolina?

11 A. Hilton Head.

12 Q. And you flew here to Hilton Head (sic) at our request to  
13 testify?

14 A. Correct.

15 Q. What has been your involvement in this case?

16 A. You contacted my company, Jason and Jarvis Associates,  
17 about getting expert consulting.

18 Q. What is Jason and Jarvis?

19 A. It's a two-person consulting company that my husband and I  
20 started ten years ago when we left the U.S. Centers For Disease  
21 Control in Atlanta.

22 Q. And what is your profession and the profession of your  
23 business partner?

24 A. We're both pediatricians, and we're both epidemiologists.

25 Q. How much of your business in, oh, let's say the last two or

1 three years involves litigation, how much of your income?

2 A. Our income, I would guess -- he's our CFO, so he's better.

3 But I would think about maybe 25 percent.

4 Q. And who hired you to look at this case?

5 A. Your firm which is Lommen Abdo.

6 Q. What did we ask you to do?

7 A. You asked me to review material and see if I was able to  
8 give an opinion on whether Jeanine Kunkel's infection,  
9 cronobacter infection, was due to powdered infant formula that  
10 was contaminated before it left the factory.

11 Q. How are you compensated for this task?

12 A. On an hourly basis.

13 Q. Does your compensation depend on the outcome of this case?

14 A. No.

15 Q. Have you ever testified in a courtroom like this before in  
16 front of a jury?

17 A. No.

18 Q. Tell the jury your areas of expertise, your specific areas.

19 A. I am a pediatrician. I'm an immunologist. I'm an  
20 infectious disease specialist. I am an epidemiologist. I have  
21 a background in health communications and also in analyzing  
22 complex study designs.

23 MR. RATHKE: Do you think this is loud enough?

24 THE COURT: Well, are the jurors able to hear the  
25 witness?

1                   JUROR FORD: She should be a little louder.

2                   THE WITNESS: I tend to talk softly.

3                   MR. RATHKE: Does it matter which mike?

4                   THE COURT: No. And they're cranked up. Let me make  
5 sure I've got them cranked up full tilt. They are.

6                   THE WITNESS: I'll work hard.

7                   MR. RATHKE: And if you're having trouble . . .

8 BY MR. RATHKE:

9 Q. Tell the jury about your education.

10 A. I got my undergraduate degree, my bachelor's, at the  
11 University of Chicago with highest honors, went to Harvard  
12 Medical School. Then I went and did my internship and residency  
13 at the Children's Hospital of Los Angeles, did a clinical  
14 immunology fellowship at Toronto Hospital For Sick Children, and  
15 did -- and did the epidemiology fellowship program at CDC. It's  
16 called the Epidemiology Intelligence Service, and I think it's  
17 probably the best epidemiology training program in the world,  
18 but I'm biased.

19 Q. Tell us if you will the date you graduated from Harvard  
20 Medical School.

21 A. 1975.

22 Q. And then you've indicated some training and education after  
23 that. Could you kind of give us when about those things  
24 occurred.

25 A. From '76 to '77, those years I did my residency. The next

1 year was my fellowship. I then was on faculty at Yale doing  
2 very basic immunology research for two years. And then in 1980  
3 I left and went to CDC. I had wanted to do child health and was  
4 getting too caught up in basic research. And so the next two  
5 years I did the EIS program, and I stayed on at CDC after that  
6 until 2003.

7 Q. So you were an employee of CDC when you did the  
8 epidemiology training?

9 A. I was an officer in the U.S. Public Health Service assigned  
10 to CDC.

11 Q. What does that mean to be an officer in the U.S. Health  
12 Service?

13 A. It's a uniform service, and it's nonmilitary, but you have  
14 a uniform, and it's very much like the military services.

15 Q. Tell the jury, please, about your career at the CDC.

16 A. I had a number of different positions at CDC. I did both  
17 epidemiology and laboratory research. Most of it was with the  
18 Center For Infectious Diseases. The research sometimes was  
19 directly in the lab, sometimes was primarily epidemiology and  
20 analyses. I supervised groups doing that work. For a short  
21 spell I supervised a group that assessed the national AIDS media  
22 campaign and developed research techniques for communications.  
23 And I was involved in public health policy formation, prevention  
24 activities, a good deal of teaching and lecturing.

25 Q. What are your years of employment with the CDC?

1 A. 1980 to 2003.

2 Q. Where were you located? Where was your office?

3 A. It's the only federal agency that's not in the DC area.

4 It's in Atlanta, Georgia.

5 Q. Have you covered your CDC years?

6 A. It's a lot of years. I think so, yes.

7 Q. All right. Now, 2003 you leave the CDC.

8 THE COURT: Did -- I don't recall that the witness --

9 MR. RATHKE: I --

10 THE COURT: Just a second. I wasn't finished. I  
11 don't recall that the witness ever told the jury what the CDC  
12 was.

13 THE WITNESS: That's important.

14 THE COURT: Or what the definition of epidemiology is.  
15 So I know all the wizards in the courtroom know it, but, you  
16 know, we select these folks, and it's helpful if you define the  
17 terminology for them.

18 MR. RATHKE: Thank you, Your Honor.

19 THE WITNESS: Okay. CDC's full name -- and its name  
20 has changed through the years. But its current name is the  
21 Center -- now you've got me all nervous.

22 THE COURT: I have a tendency to do that to folks.

23 THE WITNESS: Oh, goodness. I'm going to move on to  
24 the second part and come back when I'm less nervous.

25 THE COURT: That's fine.

1                   THE WITNESS: Epidemiology is the science, the medical  
2 science, of looking at diseases in populations and to come up  
3 with ways to identify the causes of diseases and to prevent  
4 their occurrence.

5                   And CDC is the Center for Disease Control and  
6 Prevention, but they've stuck with the CDC and left off the P  
7 part.

8 BY MR. RATHKE:

9 Q. In addition to your CDC or as part of your CDC experience,  
10 could you tell the jury about your clinical experience.

11 A. The longest time I've spent clinically is during those 23  
12 years at CDC, I was also on faculty at Emory University School  
13 of Medicine in the department of pediatric infectious diseases,  
14 immunology and epidemiology. And in that capacity I did what's  
15 called attending where you take turns supervising medical  
16 students, residents, and fellows. You provide patient care.  
17 You do one-on-one teaching as well as lecturing. And I did --  
18 my focus in this were very sick children and how the immune  
19 system responds to various insults and how to deal with that.

20 Q. And what are you currently doing since 2003 retirement?

21 A. Since then I work pro bono part time at a free clinic.

22 Q. Where is that located?

23 A. On Hilton Head.

24 Q. Have you been published?

25 A. I've published or coauthored or authored over a hundred

1 scientific peer-reviewed papers, chapters, and one book for  
2 parents on parenting premature infants. That book was published  
3 by two big U.S. publishing companies, and then a German  
4 publisher published it in Germany.

5 THE COURT: And, doctor, would you mind defining for  
6 us the Latin phrase pro bono?

7 THE WITNESS: Yeah, it's -- I don't charge. I've  
8 never charged a patient.

9 BY MR. RATHKE:

10 Q. Do any of your publications relate to E. sak?

11 A. Yes. In 2011 and 2012 I did a series of analytic studies  
12 looking at invasive cronobacter infection in children, and the  
13 results of that were published in a journal called Pediatrics.  
14 That's the peer-reviewed journal of the American Academy of  
15 Pediatrics.

16 Q. What was the publication date?

17 A. It was, I believe, November of 2012.

18 Q. And generally what did you -- in a very general sense, what  
19 was the publication about?

20 A. The -- well, what I did was I collected all available  
21 information on any case of cronobacter that was in a pediatric  
22 patient s -- from the beginning, the first reported case which  
23 was 1958, through to the end of 2010 and to get the information,  
24 I looked at everything ever published. I contacted the authors.  
25 I went through CDC records, FDA records, legal documents,

1 reports in the literature, basically any source I could find.

2 I then separated off cases that I defined as being  
3 invasive, and it was a definition that's consistent with the  
4 literature. But the gist of it was to look at only significant  
5 infections. I characterized those cases, and then I split off  
6 the cases that occurred in previously healthy children and  
7 analyzed those further.

8 In 2002 the FDA sent a letter out to healthcare  
9 providers, and the letter cautioned them about using powdered  
10 infant formula which I don't -- I can't talk as quickly as you  
11 can. I call it PIF so I don't get tongue tied. It cautioned  
12 healthcare providers to avoid using PIF in newborns who are in  
13 newborn intensive care units or NICUs, and it was specifically  
14 because of the problem of cronobacter.

15 Over the next couple of years that information  
16 disseminated to the pediatric community. So my next analysis I  
17 looked at cases that occurred before 2004, and I compared them  
18 to ones that occurred after 2004 to see if there was any  
19 temporal association between -- any temporal changes in the  
20 characteristics of the cases that occurred before and after that  
21 time period.

22 And then the third analysis looked at the relative  
23 costs of ready-to-feed and powdered formulas.

24 Q. And we'll get into that a little bit later. But that was  
25 what you were researching in your paper.

1 A. Correct.

2 Q. Now, did you review any materials that are specific to this  
3 particular case?

4 A. I would say almost certainly, but if I did, it's not  
5 identified in the document, and I'd have to go back and look  
6 over my notes.

7 Q. Okay. Let me ask you to do this. Tell the jury what you  
8 recall reviewing about this case.

9 A. For that manuscript?

10 Q. No, no, no, no, no, no. In connection with your engagement  
11 as an expert.

12 A. Oh, my goodness. All right. Specifically for this case I  
13 reviewed CDC records, FDA records, health department records, a  
14 number of depositions of the family and of some Abbott  
15 employees, the reports and the deposition of the Abbott experts.  
16 I don't know if you mean specifically. I also did an updated  
17 literature review to see what else had happened since I last did  
18 one.

19 Q. Did you review any medical records?

20 A. Oh, yes. I reviewed the medical records of the -- of both  
21 Jeanine, her brother, and her father and her mother.

22 Q. And did you read a number of depositions from family  
23 members?

24 A. Yes, I read the depositions and the corrections to  
25 depositions of the mother, the father, and the maternal

1 grandmother.

2 Q. Did you review any documents generated by Abbott or the  
3 industry?

4 A. Yes. I reviewed a large number of documents that were  
5 related to what's called the Infant Formula Council or IFC.  
6 It's my understanding that that is an organization of different  
7 formula manufacturers predominantly from North America.

8 Q. Could the name of that organization possibly be the  
9 International Formula Council?

10 A. That is very possible.

11 Q. And in addition to the materials that are specific to this  
12 case, did you also review some, you know, general literature on  
13 the subject because of this case?

14 A. Because of -- well, yes. I mean, basically I looked to see  
15 what was new since I had already looked at everything for the  
16 manuscript.

17 Q. Do you believe that you reviewed sufficient material to  
18 reach an opinion regarding the source and cause of Jeanine's  
19 illness?

20 A. I do.

21 Q. And do you have an opinion regarding the source and cause  
22 of Jeanine's illness to a reasonable degree of medical and  
23 scientific certainty?

24 A. I do.

25 Q. And what is that opinion?

1 A. It's my opinion that it is -- that the truth is more likely  
2 than not that Jeanine's invasive cronobacter infection was due  
3 to a virulent cronobacter that was in her powdered formula  
4 before it was sealed and left the factory.

5 Q. Why do you rule in powdered infant formula as a source?

6 A. I think I have a slide for this.

7 Q. You do.

8 A. It would be slide 7. Cronobacter is what's called an  
9 enteric bacteria and in --

10 Q. Excuse me. Could you say that word a little bit --

11 A. Enteric?

12 Q. En --

13 A. En, enteric, e-n-t-e-r-i-c.

14 Q. All right. And you said it was an enteric bacteria, but  
15 you need to tell us what that means.

16 A. I was about to.

17 Q. Okay. Sorry.

18 A. That word comes from the Greek word for intestines, and the  
19 reason it's got that name is that is where an enteric bacteria  
20 likes to live. It gets in through the mouth, tries to take up  
21 residence in the intestines, and there it will divide. If it's  
22 one that doesn't cause illness, it may actually help us digest  
23 food. If it's one that causes illness, it will keep dividing.  
24 Ideally our body will fight back and just get it out of there.  
25 If you don't win the battle, it can get through the wall of the

1       intestines and go to the rest of the body.

2           So by definition this is a bacteria that gets in  
3       through the food.  Salmonella is an enteric bacteria.  E. coli  
4       is an enteric bacteria.  Jeanine Kunkel was fed ready-to-feed  
5       formulas at her birth hospital.  Ready-to-feed formulas or RTF  
6       are sterilized.  The manufacturer pasteurizes them, and that  
7       kills any bacteria that's in there.  She did perfectly well on  
8       that until she was sent home at three days of age.

9           Her mom continued to feed her ready-to-feed formula  
10      for the next six days.  And then at 9 p.m. on April 23, she gave  
11      Jeanine her first feeding of powdered formula, namely NeoSure  
12      22.  Up until then Jeanine was doing fine.  She was thriving.  
13      Her powdered formula was literally the only nonsterile thing  
14      Jeanine had been fed up until that time.

15           There is a body of research that goes back at least 30  
16      years, incredibly elegant epidemiologic research that has shown  
17      the relationship between powdered infant formulas and invasive  
18      infection with cronobacter in infants.  And by infants I mean  
19      very young infants in the first two months of life.

20           The connection has been both looking at it through  
21      straight epidemiologic techniques showing that those that have  
22      received a certain formula became infected.  Those that did not  
23      didn't to a level of significance that's beyond the likelihood  
24      of chance.

25           Some studies have in addition cultured the organism

1 and matched it to what's in the infants. But again and again  
2 between outbreak investigations and what we call sporadic cases,  
3 individual cases, the link is incredibly powerful. It is the  
4 only thing that has ever been shown to cause this infection in  
5 infants.

6                   And lastly, on the day that Jeanine's product began  
7 production in Abbott's Casa Grande plant, Abbott was doing  
8 routine environmental monitoring for contamination. This is a  
9 known contaminant in factories. It's endemic in factories. On  
10 the day her product began to be produced, Abbott had two  
11 positive cultures for enterobacter sakazakii which is what it  
12 was called back then. It was in the very place where her  
13 product was being produced.

14 Q. Abbott tested this product, this batch, before it left the  
15 plant. And its testing was negative for E. sak. Why don't  
16 those negative -- and you're aware of that; right?

17 A. I'm aware of that, yes.

18 Q. Why is it that that final product testing which was  
19 negative for E. sak, why doesn't that rule out E. sak or the  
20 powdered infant formula as the source of the E. sak?

21                   THE WITNESS: Pat, could I have slide tw -- slide 8?

22 Q. Eight.

23 A. You like 1. That's the first one.

24                   I am sure you're going to hear more about this from  
25 other experts. I could go on and on, but there are people who

1 know more about factories than I do by far.

2 This is the percent of end product that was tested by  
3 Abbott before it released the product to the market. They  
4 tested ////////////// of the product. Lots of powdered formula --  
5 and I did not know this until I got more involved in this issue.  
6 They are massive. One lot of PIF weighs over 150,000 pounds.

7 The nature of contamination with cronobacter is that  
8 it's clumped. As far back as 2003 at an FDA meeting scientists  
9 at that meeting were pointing out that this bacteria was unusual  
10 in that it kept clumping. They had trouble working with it  
11 because they couldn't get it to stop clumping so they could work  
12 with it.

13 At that very same meeting an FDA staff person who has  
14 through the years worked a lot on this topic commented that, of  
15 course, the contamination is not homogeneous, that it happens in  
16 the dry production point and it's from unintentional contam --  
17 an area or a piece of equipment will be contaminated, and  
18 inadvertently a clump of contamination will fall into the  
19 product. So it's not spread out evenly throughout the product.  
20 But the testing being done makes that assumption.

21 Nothing is a hundred percent even if the testing were  
22 done according to the kind of contamination there is. But when  
23 you have this clumped episodic contamination, this amount of  
24 testing is simply not going to be able to pick it all up.

25 MR. RATHKE: You can take that off.

1 Q. After Jeanine became sick, the can from which she was fed  
2 which had some powder in it eventually found its way to the CDC  
3 in Atlanta where it was tested, and it was determined that there  
4 was no E. sak or at least they didn't find any E. sak in that  
5 opened can. Why don't those negative results, why don't those  
6 rule out the powdered infant formula as a source of the -- of  
7 C. sak?

8 A. I think the glib answer would be because she ate it. There  
9 was f -- I should mention that Abbott's own results, if you look  
10 through their records, show that end product testing doesn't  
11 necessarily pick up all contamination. There have been times  
12 where they've tested a lot using the routine end product  
13 testing, found it to be negative, and then gone back for one  
14 reason or another and found it to be positive.

15 A paper came out in 2011 where someone did a huge  
16 amount of work looking at not an Abbott lot but a lot of  
17 contaminated product that had been released to market. And it  
18 showed what the FDA folks knew back in 2003. You would have one  
19 area with enough clumping that it could, in fact, cause severe  
20 disease while the rest of it was either only slightly  
21 contaminated or perfectly fine. And the comment of that author  
22 was that in a public health sense the implication was that some  
23 poor infant could swallow that one or two clumps and you would  
24 have a catastrophe for that one infant.

25 So that's a long way around to the glib answer that

1 you could have contamination in one small portion of a can and  
2 the rest of that can could be perfectly fine.

3 MR. RATHKE: I would like to mark for evidence a paper  
4 that has not been admitted and just display it to the witness  
5 for purposes of laying foundation.

6 Pat? It's Exhibit 151.

7 THE COURT: Just tell me again what 151 is.

8 MR. RATHKE: 151 is an e-mail.

9 THE COURT: Oh, right. Go ahead.

10 MR. RATHKE: Should I --

11 THE COURT: Yep.

12 MR. RATHKE: -- lay foundation?

13 THE COURT: Exactly.

14 MR. RATHKE: All right. Go ahead. We want to show it  
15 on this but not on the screen yet.

16 THE COURT: Let me explain to the jury what's going  
17 on. Most of the -- I should have told you this at the  
18 beginning. I've been meeting with the lawyers on and off for  
19 weeks if not months about the exhibits. And one of the things I  
20 told you in jury selection was that because we try a lot of  
21 cases in our district we do things more efficiently than most  
22 districts. So most of the exhibits are already in evidence.  
23 We've resolved objections, if any, to them, and they're already  
24 in evidence. There are a few that are not.

25 So in order to determine whether or not I should admit

1 the exhibit, they have to show it to the witness. Lawyers use  
2 this phrase they have to lay a proper foundation for it. In  
3 other words, can the witness testify to what it is that would  
4 convince me that I should admit it, and that's what's happening  
5 right now.

6 BY MR. RATHKE:

7 Q. Dr. Jason, I've put before you what's been marked as  
8 Exhibit 151. Do you see that in front of you?

9 A. Yes, yes.

10 Q. And that -- generally what that is is an e-mail from Anna  
11 Bowen identified as a CDC person to an individual named Seth  
12 Levine. Is that correct?

13 A. Correct.

14 Q. What's the date of the e-mail?

15 A. I think it's October 26, 2007.

16 Q. Do you know who Anna Bowen is?

17 A. Yes.

18 Q. Would you tell the judge and the jury who Anna Bowen is.

19 A. She is a pediatrician and an epidemiologist at CDC. She  
20 worked on enteric infections and has worked for at least eight  
21 years on this particular bacteria. She has published at least  
22 one review article and at least one chapter that I know of on  
23 this topic.

24 Q. Does she know anything about E. sak?

25 A. I would say she's -- in terms of epidemiology, I don't

1 think there's anyone who knows more than she does.

2 Q. And in the e-mail she makes some comments about an  
3 investigation that was going on in 2007. Is that correct?

4 A. Correct, yes.

5 Q. And that's not this case at all. This case had not even  
6 occurred; correct?

7 A. Correct.

8 Q. Are there some similarities between the facts in this case  
9 and the facts in the case that she was commenting about in her  
10 e-mail? Just yes or no.

11 A. Yes.

12 Q. And do you agree with the sentiments that she expresses  
13 about those similarities?

14 A. I do.

15 Q. And do they help -- are they part of the foundation for  
16 your opinion?

17 A. Yes.

18 Q. Do you recognize this e-mail as a -- you know, I know you  
19 were at the CDC. I don't know if they were doing e-mail then.  
20 Probably were. Is this a CDC e-mail?

21 A. I'm not that old. Yes, yes, definitely an e-mail.

22 MR. RATHKE: All right. I'd ask that Exhibit 151 be  
23 admitted as a relevant business record and foundation for her  
24 opinion.

25 \* \* \* \*

1 (Exhibit 151 was offered.)

2 \* \* \* \*

3 MS. GHEZZI: Your Honor, our objection stands. It's  
4 not -- I mean, business record is really not the point. I mean,  
5 we don't have her to cross-examine, and it's a year before --  
6 almost a year before the event in this case. Dr. Jason is not  
7 listed on it. She's not a recipient. It's not addressed to  
8 her.

9 THE COURT: Actually none of that makes any difference  
10 under 703, but he hasn't laid the proper foundation under 703.  
11 There's a magic question you need to ask, and you skirted around  
12 it. So do you have your rules with you, or you actually come  
13 into a federal court without the rules?

14 MR. RATHKE: We have the rules.

15 THE COURT: Well, you haven't asked the proper  
16 question under 703.

17 MR. RATHKE: Oh, I thought I covered it. Maybe I  
18 didn't.

19 BY MR. RATHKE:

20 Q. Is this something you relied upon when you reached your  
21 conclusions?

22 A. I would have the same conclusion with or without this. I'm  
23 not sure what you're asking.

24 Q. Is this a document that would be part of -- part of the --  
25 that you would have reviewed in the process of reaching your

1       opinion?

2       A.    Oh, yes, I did re -- I did see this, yes.

3       Q.    And did you in some measure rely upon that, on this  
4       document, in reaching your opinion?

5       A.    I think any intelligent person would feel more secure in  
6       their opinion if other intelligent people working in an area  
7       agree.

8       Q.    And this is in agreement with your opinion.

9       A.    Correct.

10           THE COURT: You were warm but no cigar. Why don't you  
11       go back and read the rule.

12       Q.    Is this something that an expert in your field would rely  
13       upon?

14       A.    Yes.

15           THE COURT: You're getting closer. You don't have the  
16       rules with you?

17           MR. RATHKE: I do but . . .

18           THE COURT: Well, open it up to Rule 703 and figure  
19       out what you need to ask.

20           MR. RATHKE: Wrong book.

21           THE COURT: It's in there.

22           MR. RATHKE: This is the criminal rules.

23           THE COURT: It doesn't make any difference. It's in  
24       the criminal rules too. It's the same rule of evidence for  
25       criminal and civil cases. I know you don't do criminal work,

1 but same rules of evidence apply.

2 Members of the jury, you can stand and take a stretch  
3 break.

4 I'll give you a hint. It's the eighth word of the  
5 second sentence of the rule.

6 BY MR. RATHKE:

7 Q. Would experts in your field reasonably rely upon this type  
8 of data in order to reach the conclusion that you've reached?

9 A. If it's from someone like this, yes.

10 THE COURT: So what are you looking at me for?

11 MR. RATHKE: Oh, I'm sorry.

12 THE COURT: You offering the exhibit?

13 MR. RATHKE: Yes.

14 THE COURT: I'm going to sustain the objection. I  
15 mean, she's allowed to testify that she relied on it, but it's  
16 not independently admissible as substantive evidence. She can  
17 rely -- she's already testified that she relied on it in giving  
18 her opinion, but her opinion would have been the same without  
19 it, and that she can testify to under 703. The underlying  
20 document itself is not admissible unless you meet all of the  
21 foundation requirements, and you haven't done that.

22 MR. RATHKE: May I ask her to describe the contents of  
23 the e-mail?

24 THE COURT: Sure. To the extent that she relied on  
25 it, sure.

1 BY MR. RATHKE:

2 Q. Go ahead.

3 A. I'm not sure I understand.

4 Q. Did -- the subject that we're talking about is the  
5 after-the-fact inspection of an open can which is negative for  
6 E. sak. That's the scenario that was presented in the case that  
7 involves what's been marked for identification as Exhibit 151;  
8 correct?

9 A. I gather from this conversation, yes.

10 Q. And what was Dr. Bowen's comment with respect to the fact  
11 that the open can tested negative for E. sak?

12 MS. GHEZZI: Your Honor, excuse me. I have to object  
13 because he's asking her essentially to -- I think to read -- to  
14 read the document.

15 THE COURT: I don't think he's asking her to do that  
16 at all. It's overruled.

17 MS. GHEZZI: Okay.

18 THE COURT: She's entitled to read the document. She  
19 relied on it.

20 MS. GHEZZI: No, she can read it. I mean read it out  
21 loud which is publishing it to the jury.

22 THE COURT: Well, she can summarize what it is in the  
23 document that she relied on.

24 MS. GHEZZI: Absolutely.

25 THE COURT: You're right. She can't just go ahead and

1 read it and get around my ruling that it's not admissible  
2 independently as substantive evidence. So you can summarize  
3 that portion of the document that you relied on in formulating  
4 your opinion.

5 A. That a open can was tested and was found to be negative,  
6 but Dr. Bowen indicates to the person at the health department  
7 inquiring about the results and what they mean, her response was  
8 that this unfortunately does not mean that the infant had not  
9 received contaminated material from that can because  
10 contamination is clumped, so the rest of the can could have been  
11 negative and it still could have been the source of the  
12 infection.

13 Q. Thank you. Abbott claims amongst other things that  
14 Jeanine's home environment including the people that would be in  
15 the home could be the source of her C. sak infection. Why do  
16 you rule out those sources?

17 A. I think that this will come up again later. Cronobacter  
18 does not infect a healthy human being. Many decades of clinical  
19 samples of healthy people who are not hospitalized and not  
20 infants, cronobacter never comes up. Cronobacter can what we  
21 call colonize. It can for a while live in very sick  
22 hospitalized people. Even this is very rare. We're talking  
23 about around the world maybe a hundred a year or something. But  
24 you can occasionally get a positive culture from a very ill  
25 hospitalized person, usually elderly, virtually always someone

1 who's got some immune problem because they're just so sick in so  
2 many ways. But it does not cause the kind of infection we see  
3 in newborn infants.

4 The people that Jeanine came in contact with at home  
5 were all younger and healthy people. These are not people who  
6 are going to be carrying around cronobacter.

7 Even more striking is just in the last few years  
8 there's been some work that even further supports that these  
9 infections come from powdered formula. And in that -- in some  
10 of these studies, what they did was look at the strain, the type  
11 of cronobacter, and I think I'll explain this later. I have  
12 some slides. But even -- for even the very elderly people, it  
13 is not the same strain of cronobacter that infects infants. And  
14 when I say infects infants, I mean invasive infection, the kind  
15 of infection that leads to death and meningitis.

16 Q. Going on to another topic, would you tell the jury a little  
17 bit more about this bacteria known as enterobacter sakazakii?

18 A. Sure. Actually I think its father is going to be here  
19 later in the week. Could I have slide 1, the one that you keep  
20 wanting to give me?

21 Enterobacter sakazakii was identified in 1980 by a  
22 microbiologist named James Farmer who at the time was working at  
23 CDC. And he characterized the bacteria, recognized its  
24 similarities to other enterobacteriaceae, the group that  
25 included salmonella and E. coli, and so he put it into the

1 family. And here we're talking about what you call taxonomy.  
2 It doesn't change anything about the bacteria. It's just a  
3 matter of deciding what family it lives in.

4 And enterobacteriaceae is what's called a genus. And  
5 a genus is kind of like an extended family if you were to have a  
6 huge family reunion. So he put it in the extended family of  
7 enterobacteriaceae. And could I have the next slide?

8 In 2008 mainly because of this issue more and more --  
9 we're not talking about a huge number of people, but there's  
10 some very good labs now that are looking at cronobacter  
11 infections, and in 2008 a number of people working very actively  
12 identified so many different variations that they decided it was  
13 time to give cronobacter its own family.

14 And so enterobacteriaceae sakazakii which is what  
15 James Farmer had called it was given a new name. And the new  
16 name was cronobacter. And that name was picked because Crono is  
17 a Greek god who ate his own children. And they subdivided the  
18 bacteria into seven different species. So species would be like  
19 a real family, a father, mother, brother, sisters. So if I  
20 could have that slide.

21 So what you have with cronobacter is -- I'm not sure  
22 how you do this with -- behind you. I'm new to this. Usually I  
23 can look at a slide -- okay. All right. What -- actually you  
24 can put that down for one second. I want to show something. Do  
25 you see my finger? You don't see anything, do you? Okay.

1       We're going to have to just kind of picture this.

2               You see seven different clusters there and then little  
3       clusters, little circles around those clusters. The seven big  
4       clusters are what we call species, so that would be like your  
5       family, your brother's family, your sister's family.

6               The little clusters are clusters that are identified  
7       because even within those families we're not alike.

8               The biggest cluster is *C. sakazakii*, and now you could  
9       highlight that. That's big because the most disease comes from  
10      *C. sakazakii*, so they have the most stored isolates. Isolates  
11      are where you collect a sample, you store it so you can study  
12      it.

13               So that's the biggest because that -- it causes the  
14       most trouble.

15               What used to be called *enterobacter sakazakii* now is  
16       called *cronobacter sakazakii*, and all of those are in this  
17       family. The other families -- if you take that down, the other  
18       fa -- the others, many of them, most of them don't do anything.  
19       They don't get in the human body. They don't do anything to us.  
20       If we ever meet one, it's just going to pass right on through  
21       us. A few of them are the ones that can cause mild problems in  
22       old people who are hospitalized and who have bigger problems to  
23       deal with. But when it comes down to invasive infection in an  
24       infant, those are -- almost universally with maybe one or two  
25       rare cases, mild exceptions, those are all *C. sakazakii*.

1 Q. So what kind of people get cronobacter infections?  
2 A. Okay. Well, as I've just said, if you are a infant less  
3 than two months of age and unlucky enough to come -- and let me  
4 take it even one step further. Within that group that says  
5 C. sakazakii, there are not that many of those even that can  
6 cause invasive infections. There is -- one of the labs doing  
7 very interesting work now is trying to identify which of these  
8 bacteria do cause very bad infections. And one lab has  
9 identified a genetic sequence that they've called sequence type.  
10 And they've put different isolates into different groups of  
11 sequence types.

12 So, for instance, if you -- it would be like dividing  
13 people up into the ones that have blond hair or black hair or  
14 gray hair. And then they look back and say, all right, I've got  
15 these into groups. Is there anything unique about these groups?

16 So let's say I've grouped everybody by hair color and  
17 I look at the people with gray hair and I say, oh, they're all  
18 old. Well, that's what they did with the strain type. They  
19 typed out -- and those are the little circles you see. This  
20 is -- that's the lab that made -- that identified all these  
21 different groups.

22 Well, within those little groups, there is one that  
23 they've numbered ST4. ST4 and its very close relatives are  
24 virtually the only one that causes severe invasive meningitis in  
25 very young infants. Most of the others don't do anything. A

1 few of the others cause either mild disease or they go along for  
2 the ride with very sick, very old people.

3                   So they have narrowed down the type of cronobacter  
4 sakazakii that causes these very severe infections. And what  
5 they have found is if they look at the isolates, they find that  
6 isolate in two big groups: Very young infants with meningitis  
7 and severe infection and powdered infant formula.

8                   They find these other ones in other foods. It is in  
9 foods. There are certain cronobacter in -- they like cereal.  
10 They like spice. But those are not the ones that infect kids.  
11 Those are generally -- if they're in powdered formula, they  
12 don't cause any harm. So they have narrowed it down to a very  
13 specific family, close, close family of cronobacter.

14                   And if you could put -- I know I didn't tell you this,  
15 but could you put up slide 57? I had a long time sitting  
16 outside, and I saw a couple slides that would hopefully --

17                   MS. GHEZZI: Your Honor, can I just -- I mean, it's a  
18 narrative. I'm fine with that. But is there a -- was there a  
19 question?

20                   THE COURT: That's --

21                   MS. GHEZZI: I mean --

22                   THE COURT: Right. I get your point. It's --  
23 objection's sustained. You don't have to make faces and roll  
24 your eyes. You can just make your objection.

25                   THE WITNESS: So should I stop?

1                   THE COURT: No. I was talking to the defense lawyer.  
2                   You need to ask a question.

3                   MR. RATHKE: All right.

4 BY MR. RATHKE:

5 Q. Why do they call it ST4? Could you be a little bit more  
6 specific as to what an ST4 -- what that stands for and what that  
7 means?

8 A. ST4, the only -- I think the only way it got to be ST4 is  
9 that they happened to -- that may be the fourth one they  
10 identified. It -- in and of itself the 4 doesn't mean anything.

11 Q. What's the sequence strain? What does that mean?

12 A. The sequence type?

13 Q. Yeah, the sequence --

14 A. That's the genetic area they were looking at. And I think  
15 we'll get into this later because it's important in terms of who  
16 gets infected and how and how much it takes to get infected.

17                   But organisms that cause -- or bacteria that cause  
18 very bad infections are called virulent bacteria. And  
19 scientists look for what makes one virulent and another one not.  
20 The people that are doing the ST4 work know that this sequence  
21 is not what makes them virulent. They just know it's for some  
22 reason linked to the bacteria that causes this problem, and  
23 that's in terms of everything I've said is not important, but if  
24 you were doing research on this topic and you wanted to know how  
25 to stop the infection, it would be important.

1 Q. Okay. We've talked about the virulent factor of ST4. Are  
2 there other virulent factor that -- factors involving  
3 *cronobacter sakazakii* which can create more virulent results?

4 A. Yes. I don't think I will show you slide 57. You know  
5 what? If I could have slide 12. There's a factor that's  
6 very -- it's very pertinent to this case because one thing that  
7 will come up -- two things that will come up is something called  
8 incubation period. An incubation period is the time between  
9 when the bacteria gets into the body and when the person becomes  
10 symptomatic. That's the definition of incubation period.

11                   And for this particular -- for the invasive  
12 *cronobacters*, it can be for some strains very, very, very short.  
13 The other issue is how much of a virulent bacteria can cause an  
14 infection. It varies from bacteria to bacteria, from strain to  
15 strain. But for some *cronobacter*, it can take a ridiculously  
16 small amount to have an impact.

17                   And this is another lab. So there's one group of labs  
18 working on strain type. Another lab has worked on a protein on  
19 the surface of some bacteria. And they've called it outer  
20 membrane protein A or OmpA, and this is a true virulence factor.  
21 And you'll see in a minute I'll explain why.

22                   But what they did with this is they did an experiment  
23 where they took bacteria that had OmpA on their surface and they  
24 took bacteria that didn't have OmpA on their surface and they  
25 reconstituted powdered formula and they put one or the other

1 into the powdered formula. And they put very tiny amounts.  
2 We're talking about no more than a hundred cells to a thousand  
3 cells so very, very -- something that you would easily have at  
4 least that many in a clump of what can get into powdered infant  
5 formula.

6 And what they found was -- and they put it into -- the  
7 animal model for this infection is a newborn mouse. So they fed  
8 it to newborn mice, and what they found was if they fed these  
9 very tiny amounts of the bacteria that had OmpA on their  
10 surface, within 6 hours it was in their brain. Within 12 hours,  
11 the poor little mice were lying on their back with their feet up  
12 in the air. They were not dead, but these were not healthy  
13 mice. They were not looking good.

14 The mice that got the bacteria without the OmpA on the  
15 surface were perfectly fine. They weren't infected at all.  
16 They were just -- they were doing very, very well.

17 They then put OmpA on the surface of the bacteria that  
18 didn't have it, and the mice got sick just like they did if it  
19 was a bacteria that naturally had it. So that's what a true  
20 virulence factor is. You know that OmpA is helping that  
21 bacteria get where it doesn't belong.

22 And I think in terms of this case it also shows how  
23 very little bacteria you need if it's a virulent bacteria to  
24 cause a very severe infection and how quickly a very virulent  
25 strain can divide in the intestines, get through the intestinal

1 wall, and cause severe infection.

2 THE COURT: Mr. Rathke, I think now would be a good  
3 time to -- you're not going to finish your examination in the  
4 next 30 seconds I take it.

5 MR. RATHKE: (Shook head.)

6 THE COURT: Okay. Members of the jury, that's going  
7 to conclude the evidence for today. I just wanted to remind you  
8 of a couple of things. We'll be using the 8:30-to-2:30 schedule  
9 tomorrow, so we'd ask you to be here a couple of minutes early.  
10 You don't have to come super early, but we can't start without  
11 all eight. So we'd like you to be here a few minutes early  
12 because I think you'll find that I tend to start on time.

13 It's very important to keep an open mind till you've  
14 heard all of the evidence in the case, and that's going to be  
15 some time down the road.

16 I brought my jumper cables, so if anybody has a hard  
17 time starting your car, you come back to the courthouse, let the  
18 court security officers know down at the front station, and  
19 either they will take my cables or I will stick around until I'm  
20 sure all of you have left because we don't want anybody to be  
21 stranded. So thank you for paying careful attention. And we'll  
22 see you tomorrow morning at 8:30. Thank you.

23 (The jury exited the courtroom.)

24 THE COURT: Please be seated. I expect the lawyers to  
25 have the rules handy. I expect you to know the rules. You

1 shouldn't even have to open it up, but you ought to have them  
2 handy in the event you don't know the rule.

3 Miss Ghezzi, you made a speaking objection. Here's  
4 what you said. Your Honor, can I just -- I mean, it's a  
5 narrative. I'm fine with that. Yeah, really? You're fine with  
6 that, and that's why you're making the objection. And then you  
7 go on to say -- let's see. I lost it here. I'm fine with that.  
8 But was there a question?

9 Here's what I expect you to do: Objection, narrative.  
10 That's all you have to say.

11 MS. GHEZZI: Okay.

12 THE COURT: And it was a narrative.

13 MS. GHEZZI: Okay.

14 THE COURT: And much of her testimony has been a  
15 narrative, probably because she's not a professional expert  
16 witness like I assume we're going to see later in the case.  
17 Well, I don't know who's going to call them, but I'd be  
18 surprised if we don't see some experts who make a good chunk of  
19 their living from being paid to testify in court. You almost  
20 always see those in products cases.

21 So you're going to need to explain to your witness  
22 what it means to go on the narrative, and then you're going to  
23 have to do a better job of asking a precise question so that she  
24 can answer that question and not go off into what she thinks the  
25 next three or four questions you're going to be answering are.

1                   Just for Dr. Jason's benefit, a witness can only  
2 answer the question asked, and they can't like go on and do  
3 these long explanations. We call that a narrative. So -- and  
4 it's not necessarily -- I'm not blaming anybody, but if the  
5 lawyers ask a very precise question, you can answer that  
6 question, then wait for the next question. And you should be  
7 able to get everything you want to get out if they ask the right  
8 questions. But that's up to the lawyers.

9                   THE WITNESS: So if they ask something that would be  
10 on a slide, am I allowed to show a slide?

11                   THE COURT: Well, you're allowed to show the slides,  
12 but you're not allowed to like keep changing gears and then talk  
13 about this study and that study when he hasn't asked you about  
14 this study or that study.

15                   THE WITNESS: Oh, okay.

16                   THE COURT: Yeah. So in other words, from your  
17 perspective, you need to listen carefully to the question and  
18 answer only the question that gets asked of you.

19                   THE WITNESS: Does he have to ask about a specific  
20 study?

21                   THE COURT: Well, not necessarily. If he asks what's  
22 your opinion about this and you rely on several studies, you can  
23 talk about them. But you have to try and be responsive to the  
24 question that he asks.

25                   THE WITNESS: Okay.

1                   THE COURT: And it just takes some practice so . . .  
2                   Anything else we need to take up before we see  
3 everybody at 8:30?

4                   MR. RATHKE: No, Your Honor.

5                   THE COURT: Anything from the defense?

6                   MR. REIDY: No, Your Honor.

7                   THE COURT: Okay. We'll see you tomorrow morning.  
8 I'll meet with the lawyers. I'm here very early. If things  
9 arise and there's a problem, then I expect you to send me an  
10 e-mail, give me a heads-up, and be here early so we can take it  
11 up because at 8:30, I don't care if the earth is falling with  
12 regard to some problem you all perceive we're having, I'm  
13 bringing the jury in. If you haven't figured that out yet,  
14 that's the trick to getting along with me. I don't keep the  
15 jury waiting, period. And if you have some new instant  
16 emergency that you could have had at four o'clock in the morning  
17 and e-mailed me or come into the courthouse, that's your  
18 problem. It's not my problem. I'm not keeping the jury  
19 waiting, period. So we'll see you tomorrow.

20                   (The foregoing trial was adjourned at 4:47 p.m.)  
21                   CERTIFICATE

22                   I certify that the foregoing is a correct copy of the  
23 transcript originally filed with the Clerk of Court on 3-20-14  
24 incorporating redactions of personal identifiers and any other  
25 redactions ordered by the Court in accordance with  
Administrative Order 08-AO-0009-P.

24                   \_\_\_\_\_  
25                   S/Shelly Semmler  
\_\_\_\_\_  
Shelly Semmler, RMR, CRR

4-29-14  
\_\_\_\_\_  
Date

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JANINE JASON

MR. RATHKE

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